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 December 31, 2024

OR

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

OR

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

Date of event requiring this shell company report

For the transition period from _____ to _____

Commission file number: 001-38764

APTORUM GROUP LIMITED
(Exact Name of Registrant as Specified in its Charter)

N/A
(Translation of Registrant's Name into English)

Cayman Islands
(Jurisdiction of Incorporation or Organization)

Ian Huen, Chief Executive Officer
Aptorum Group Limited
17 Hanover Square, London W1S 1BN, United Kingdom
Tel: +44 20 8092 9299
Fax: +44 20 3928 8277
(Address of principal executive offices and Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Class A Ordinary shares, par value $0.00001	APM	NASDAQ Capital Market

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

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

Class A Ordinary Shares: 3,811,823

Class B Ordinary Shares: 1,796,934

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 every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards+ provided pursuant to Section 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 whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If the securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

Unless the context otherwise requires, in this annual report on Form 20-F references to:

- "505(b)(2) Application" refers to an application for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted" (21 U.S.C. 355(b)(2)).

- "A*STAR" refers to Agency for Science, Technology and Research.

- "Acticule" refers to Acticule Life Sciences Limited, an 80% owned subsidiary of Aptorum Group.

- "Aeneas Group" refers to Aeneas Limited and its subsidiaries. Aeneas Limited is 76.8% owned by Jurchen Investment Corporation. Because Mr. Huen, a director, holds 100% equity interest in Jurchen Investment Corporation, we refer Aeneas Group as a fellow subsidiary of Aptorum Group.

- "AML" refers to Aptorum Medical Limited, a 90% owned subsidiary of Aptorum Group, as of the date of this report.

- "AML Clinic" refers to an outpatient medical clinic operated by AML under the name of Talem Medical.

- "Aptorum Group," and "Group" refer to Aptorum Group Limited, a Cayman Islands exempted company with limited liability whose principal place of business is in Hong Kong, all of its subsidiaries and the consolidated VIEs to which we are regarded as the primary beneficiary for accounting purposes.

- "At The Market Offering" or "ATM Offering" refers to the offering and sale of the Company's Class A Ordinary Shares, offered pursuant to the prospectus supplement and the accompanying prospectus to the registration statement on Form F-3 (File No. 333-268873), in which H.C. Wainwright & Co., LLC ("Wainwright"), acted as the Company's sales agent in accordance with certain at the market offering agreement (the "Sales Agreement"), dated as of March 26, 2021, by and between the Company and Wainwright.

- "cGCP" refers to Current Good Clinical Practice as adopted by the applicable regulatory authority.

- "cGLP" refers to Current Good Laboratory Practice as adopted by the applicable regulatory authority.

- "cGMP" refers to Current Good Manufacturing Practice as adopted by the applicable regulatory authority.

- “Class A Ordinary Shares” refers to the Company’s Class A Ordinary Shares, par value $0.00001 per share.
- “Class B Ordinary Shares” refers to the Company’s Class B Ordinary Shares, par value $0.00001 per share.
- “Company,” “we” and “us” refer to Aptorum Group Limited, a Cayman Islands exempted company with limited liability whose principal place of business is in Hong Kong.
- “CMC” refers to chemical, manufacturing and control.
- “Covar” refers to Covar Pharmaceuticals Incorporated, a contract research organization engaged by the Company.
- “CROs” refers to contract research organizations.
- “CTA” refers to Clinical Trial Application.
- “EEA” refers to the European Economic Area.
- “EMA” refers to the European Medicines Agency.
- “EMEA” refers to Europe, the Middle East and Africa.
- “EPO” refers to the European Patent Organization or the European Patent Office operated by it.
- “European Patent” refers to patents issuable by the EPO.
- “EU” refers to the European Union.
- “Exchange Act” refers to the U.S. Securities Exchange Act of 1934, as amended.
- “FDA” refers to U.S. Food and Drug Administration.
- “FDCA” refers to the U.S. Federal Food, Drug and Cosmetic Act.
- “Fiscal year” refers to the period from January 31 of each calendar year to December 31 of the following calendar year.
- “HKD” refers to Hong Kong Dollars.
- “Hong Kong” or “H.K.” refers to Hong Kong Special Administrative Region of the People’s Republic of China.
- “Hong Kong Doctors” refers to the doctors in Hong Kong under the employment of AML Clinic.
- “IND” refers to Investigational New Drugs.
- “IP” refers to intellectual property.
- “IPO” or “Offering” means the initial public offering by the Company of 76,142 Class A Ordinary Shares consummated on December 17, 2018.
- “Jurchen” refers to Jurchen Investment Corporation, a company wholly owned by one of our directors and former CEO, Ian Huen, and a holding company of Aptorum Group.
- “Lead Projects” refers to ALS-4, SACT-1 and Paths^{Dx} Test.
- “Libra” refers to Libra Sciences Limited, a VIE in which we hold 97.27% economic interest and 31.51% voting power. Libra is incorporated under the laws of the Cayman Islands. We are not deemed as the primary beneficiary of Libra for accounting purposes.
- “Major Patent Jurisdictions” refers to the United States, member states of the European Patent Organization and the People’s Republic of China.
- “Mios” refers to Mios Pharmaceuticals Limited, a previously consolidated VIE in which we indirectly held 97.93% economic interest and 36.17% voting power. Aptorum was regarded as the primary beneficiary of Mios for accounting purposes. During the year of 2024, Mios was dissolved and ceased operations; it was therefore deemed disposed by the Group.

- “Nativus” refers to Nativus Life Sciences Limited, a wholly owned subsidiary of Aptorum Group.
- “NMPA” refers to China’s National Medical Products Administration and its predecessor, the China Food and Drug Administration.
- “NDA” refers to a New Drug Application issued by the FDA.
- “Ordinary Shares” refers to the Class A Ordinary Shares and Class B Ordinary Shares collectively.
- “PRC” and “China” refer to the People’s Republic of China.
- “Registered Direct Offering” means the registered direct offering by the Company of 135,135 Class A Ordinary Shares and warrants to purchase up to 135,135 Class A Ordinary Share consummated on February 28, 2020.
- “Restructure” refers to the Company’s change from an investment fund with management shares and non-voting participating redeemable preference shares to a holding company with operating subsidiaries, effective as of March 1, 2017.
- “Registration Statement” refers to the Company’s Registration Statement on Form F-1 (File No. 333-227198) for the sale of up to 349,397 Class A Ordinary Shares (including Class A Ordinary Shares underlying certain warrants and a bond, as fully described therein) which initially filed on September 5, 2018 and became effective on December 3, 2018.
- “R&D” refers to research and development.
- “R&D Center” refers to an in-house pharmaceutical development center located in Hong Kong Science and Technology Park.
- “Securities Exchange Commission,” “SEC,” “Commission” or similar terms refer to the Securities Exchange Commission.
- “Sarbanes-Oxley Act” refers to the Sarbanes-Oxley Act of 2002.
- “Scipio” refers to Scipio Life Sciences Limited, originally a consolidated VIE in which we indirectly hold 97.93% economic interest and 35.06% voting power, and Aptorum is regarded as the primary beneficiary of Scipio for accounting purposes. In November 2024, the Group acquired 10,000 Class A Ordinary Shares and 5,850,000 Class B Ordinary Shares of Scipio, achieving control over the entity. As a result of this acquisition, Scipio is no longer classified as a VIE under the Group and it became a subsidiary under the Group.
- “Securities Act” refers to the Securities Act of 1933.
- “UK” refers to the United Kingdom.
- “United States,” “U.S.” and “US” refer to the United States of America.
- “Videns” refers to Videns Incorporation Limited, a wholly owned subsidiary of Aptorum Group.
- “VIE” refers to a variable interest entity.
- “US$,” “U.S. dollars,” or “dollars” are to the legal currency of the United States.

Discrepancies in any table between the amounts identified as total amounts and the sum of the amounts listed therein are due to rounding.

This annual report on Form 20-F includes our audited consolidated balance sheets as of December 31, 2024, and 2023, and the related consolidated statements of operations and comprehensive loss, equity and cash flows for the years ended December 31, 2024, 2023, and 2022.

Our operations and equity are funded in U.S. dollars, and we currently incur the majority of our expenses in U.S. dollars or in H.K. dollars. H.K. dollar is currently pegged to the U.S. dollar; however, we cannot guarantee that such peg will continue to be in place in the future. Our exposure to foreign exchange risk primarily relates to the limited cash denominated in currencies other than the functional currencies of each entity and limited revenue contracts dominated in H.K. dollars in certain PRC operating entities. We do not believe that we currently have any significant direct foreign exchange risk and have not hedged exposures denominated in foreign currencies or any other derivative financial instruments.

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. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report on Form 20-F and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition, results of operations and growth prospects could be materially adversely affected by any of these risks. This 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 "Special Note Regarding Forward-Looking Statements" below.

Summary Risk Factors

The following summarizes some, but not all, of the risks provided below. Please carefully consider all of the information discussed in this Item 3.D. "Risk Factors" in this annual report for a more thorough description of these and other risks.

Risks Related to Doing Business in Hong Kong

- Risks relating to legal and regulatory risks associated with our operations in Hong Kong.

- If we become directly subject to the recent scrutiny, criticism and negative publicity involving U.S.-listed Chinese companies, we may have to expend significant resources to investigate and resolve the matter which could harm our business operations, stock price and reputation and could result in a loss of your investment in our stock, especially if such matter cannot be addressed and resolved favorably.

- The recent joint statement by the SEC, proposed rule changes submitted by Nasdaq, and an act passed by the U.S. Senate and the U.S. House of Representatives, all call for additional and more stringent criteria to be applied to emerging market companies. These developments could add uncertainties to our offering, business operations, share price and reputation.

- Our business, financial condition and results of operations, and/or the value of our Class A Ordinary Shares or our ability to offer or continue to offer securities to investors may be materially and adversely affected to the extent the laws and regulations of the PRC become applicable to a company such as us.

- Our Class A Ordinary Shares may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors. The delisting of our Class A Ordinary Shares, or the threat of their being delisted, may materially and adversely affect the value of your investment. Furthermore, on December 29, 2022, a legislation entitled "Consolidated Appropriations Act, 2023" (the "Consolidated Appropriations Act"), was signed into law by President Biden. The Consolidated Appropriations Act contained, among other things, an identical provision to the Accelerating Holding Foreign Companies Accountable Act (the "AHFCAA"), which reduces the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three years to two.

- Even though our auditor is based in New York, New York and under full inspection by the PCAOB and that it is not currently subject to the determinations announced by the PCAOB on December 16, 2021, if any PRC law relating to the access of the PCAOB to auditor files were to apply to a company such as us or its auditor, the PCAOB may be unable to fully inspect our auditor, which may result in our securities being delisted or prohibited from being traded "over-the-counter" pursuant to the HFCA Act and materially and adversely affect the value and/or liquidity of your investment.

- The uncertainties with respect to the Chinese legal system, including uncertainties regarding the enforcement of laws, and sudden or unexpected changes in laws and regulations in China with little advance notice could adversely affect us and limit the legal protections available to you and us.

Risks Related to the Preclinical and Clinical Development of Our Drug Candidates

- Risks relating to not generate sufficient revenue

- Risks relating to uncertainty in preclinical development process

- Risks relating to fail to identify additional drug candidates

- Risks relating to conduct clinical trials in or outside the U.S.

Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

- Risks relating to fail or delay to obtain regulatory approval

- Risks relating to undesirable adverse event

- Risks relating to fail to complete the 505(b)(2) pathway for the pediatric formulation

- Risks relating to our third-party suppliers fail to comply with the FDA's good manufacturing practice regulations or fail to respond to an FDA Form 483 or subsequent Warning Letter

Risks Related to Commercialization of Our Drug Candidates

- Risks relating to fail to achieve market acceptance

Risks Related to Our IP

- Risks relating to being unaware of others' pending patent applications
- Risks relating to unable to protect and enforce our IP rights throughout the world
- Risks relating to lawsuits for protecting our IP or against infringing IP rights of other parties
- Risks relating to non-compliance with patent protection requirements or obligations in the license agreements
- Risks relating to the terms and scope of our patents not sufficient to protect our candidates
- Risks relating to unable to obtain or maintain rights of the developing technology through acquisitions or licenses

Risks Related to Our Reliance on Unrelated Parties

- Risks relating to manufacturers fail to provide sufficient quantities of clinical supply on our candidate at acceptable quality levels or prices

Risks Related to Our Industry, Business and Operation

- Risks relating to not complying with laws
- Risks relating to difficulties in managing our growth
- Risks relating to unable to collaborations, strategic alliances or acquisitions or enter into royalty-seeking or sublicensing arrangements
- Risks relating to our disclosure controls and procedures and internal financial reporting controls
- Risks relating to do business internationally
- Risks relating to product liability lawsuits arise from clinical trials
- Risks relating to inadequate insurance coverage
- Risks relating to failure in safeguarding our computer network system
- Risks relating to outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease

Risks Related to Our Corporate Structure

- Risks relating to our Class B shareholders have higher voting rights

Risks Related to our Securities

- Risks relating to certain existing shareholders have substantial influence over our Company and their interests may not be aligned with the interests of our other shareholders
- Risks relating to conduct substantially all of our operations outside the United States
- Risks relating to adopt certain home country practices or take advantage of certain reduced reporting requirements
- We have ceased to qualify as an "emerging growth company" and will incur increased costs as a result.

Risks Related to the Preclinical and Clinical Development of Our Drug Candidates

We currently do not generate revenue from product sales and may never become profitable; unless we can raise more capital through additional financings, of which there can be no guarantee.

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, the drug candidates in our Lead Projects and any future drug candidates we may develop, as we do not currently have any drugs that are available for commercial sale. We expect to continue to incur losses before commercialization of our drug candidates and any future drug candidates. None of our drug candidates has been approved for marketing in the U.S., Europe, the PRC or any other jurisdictions and may never receive such approval. Our ability to generate revenue and achieve profitability is dependent on our ability to complete the development of our drug candidates and any future drug candidates we develop in our portfolio, obtain necessary regulatory approvals, and have our drugs products under development manufactured and successfully marketed, of which there can be no guarantee. We may not be able to generate a profit until our drug candidates become profitable.

Even if we receive regulatory approval and marketing authorization for one or more of our drug candidates or one or more of any future drug candidates for commercial sale, a potential product may not generate revenue at all unless we are successful in:

- developing a sustainable and scalable manufacturing process for our drug candidates and any approved products, including establishing and maintaining commercially viable supply relationships with third parties;
- launching and commercializing drug candidates following regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our drug candidates as viable treatment options;
- addressing any competing technological and market developments;
- negotiating and maintaining favorable terms in any collaboration, licensing or other arrangement into which we may enter to commercialize drug candidates for which we have obtained required approvals and marketing authorizations; and
- maintaining, protecting and expanding our portfolio of IP rights, including patents, trade secrets and know-how.

In addition, our ability to achieve and maintain profitability depends on timing and the amount of expenses we will incur. Our expenses could increase materially if we are required by the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities to perform studies in addition to those that we currently have anticipated. Even if our drug candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products.

Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenues from the sale or sublicense of any products we may develop or license, we may not become profitable on a sustainable basis or at all. Our failure to become and remain profitable would decrease the value of our Company and adversely affect the market price of our Class A Ordinary Shares, which could impair our ability to raise capital, expand our business or continue our operations.

Preclinical development is a long, expensive and uncertain process, and we may terminate one or more of our current preclinical development programs.

Traditionally, drug discovery and development is a time-consuming, costly and high-risk business. On average, the cost of launching a new drug is estimated to approach US$2.6 billion and can take around 12 years to make it to the market (4 key benefits of drug repositioning. (n.d.). Retrieved from http://www.totalbiopharma.com/2012/07/04/4-key-benefits-drug-repositioning/). Despite the huge expenditures, only approximately 1 in 1,000 potential drugs is graduated to human clinical trials after pre-clinical testing in the United States, (Norman, G. A. Drugs, Devices, and the FDA: Part 1. JACC: Basic to Translational Science, 1(3), 170-179, 2016) and nearly 86.2% of drug candidates entering phase 1 trials fails to achieve drug approval. (Wong C. H., Siah K. W. & Lo A. W. (2019, April), "Estimation of clinical trial success rates and related parameters," retrieved from https://academic.oup.com/biostatistics/article/20/2/273/4817524). Even after a drug is commercialized, there are just too many factors affecting the sales of pharmaceutical products, including unmet need/burden of disease (68.2%), clinical efficacy (47.3%), comparator choice (36.4%), safety profile (36.4%), and price (35.5%) (Sendyona, S., Odeyemi, I., & Maman, K. "Perceptions and factors affecting pharmaceutical market access: Results from a literature review and survey of stakeholders in different settings" Journal of Market Access & Health Policy, 4(1), 31660, 2016). In the end, on average, only 20% of approved new drugs generate revenues that exceed the average R&D investment. (Rosenblatt, M. (2014, December 19) "The Real Cost of "High-Priced" Drugs," retrieved from https://hbr.org/2014/11/the-real-cost-of-high-priced-drugs). We may determine that certain preclinical product candidates or programs do not have sufficient potential to warrant the allocation of resources toward them. Accordingly, we may elect to terminate our programs for and, in certain cases, our licenses to, such product candidates or programs. If we terminate a preclinical program in which we have invested significant resources, we will have expended resources on a program that will not provide a full return on our investment and missed the opportunity to have allocated those resources to potentially more productive uses.

Management has discretion to terminate the development of any of our projects at any time.

In light of the costs, both in time and expense, as well as the preclinical results and general business considerations, management may decide not to continue developing a particular preclinical program without announcement. Management will always base its decision on what it believes to be the most efficient use of the Company's resources to provide the most value to its shareholders. As a result, investors may not always be aware of the termination of a previously announced study or trial. The Company will continue to provide update on its active preclinical projects in its SEC filings and/or press releases, as appropriate.

We may not be successful in our efforts to identify or discover additional drug candidates. Due to our limited resources and access to capital, we must continue to prioritize development of certain drug candidates; such decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities in addition to the drug candidates that we are currently developing, we may fail to identify other drug candidates for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other undesirable characteristics that make them unmarketable or unlikely to receive regulatory approval.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we have chosen to focus at present on our three Lead Projects, which may ultimately prove to be unsuccessful. As a result of this focus, we may forego or delay pursuit of opportunities with other drug candidates, or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Even if we determine to pursue alternative therapeutic or diagnostic drug candidates, these other drug candidates or other potential programs may ultimately prove to be unsuccessful. In short, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to develop suitable potential drug candidates through internal research programs. This could materially adversely affect our future growth and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Although we obtained CTA/FDA approval to initiate clinical trials for our Lead Projects, there can be no assurance, timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who meet the trial criteria and remain in the trial until its conclusion. We may experience difficulties enrolling and retaining appropriate patients in our clinical trials for a variety of reasons, including but not limited to:

- the size and nature of the patient population;
- patient eligibility criteria defined in the clinical protocol;
- the size of study population required for statistical analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial and changes to the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics exist and will reduce the number and types of patients available to us;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- patients enrolled in clinical trials may not complete a clinical trial; and
- the availability of approved therapies that are similar to our drug candidates.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Clinical drug development involves a lengthy and expensive process and could fail at any stage of the process. We have limited experience in conducting clinical trials and results of earlier studies and trials may not be reproduced in future clinical trials.

For our drug candidates, clinical testing is expensive and can take many years to complete, while failure can occur at any time during the clinical trial process. The results of studies in animals and early clinical trials of our drug candidates may not predict the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through studies in animals and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations (including genetic differences), patient adherence to the dosing regimen and the patient dropout rate. Results in later trials may also differ from earlier trials due to a larger number of clinical trial sites and additional countries and languages involved in such trials. In addition, the design of a clinical trial can determine whether its results will support approval of a drug candidate, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced and significant expense has been incurred.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of demonstrated efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. Furthermore, if the trials we conduct fail to meet their primary statistical and clinical endpoints, they will not support the approval from the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities for our drug candidates. If this occurs, we would need to replace the failed study with new trials, which would require significant additional expense, cause substantial delays in commercialization and materially adversely affect our business, financial condition, cash flows and results of operations.

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

Before applying for and obtaining regulatory approval for the sale of any of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and may fail. A failure of one or more of our clinical trials can occur at any stage of testing and successful interim results of a clinical trial do not necessarily predict successful final results.

We and our CROs are required to comply with current Good Clinical Practices ("cGCP") requirements, which are regulations and guidelines enforced by the FDA, NMPA, EMA, Health Canada and other comparable regulatory authorities for all drugs in clinical development. Regulatory authorities enforce these cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. Compliance with cGCP can be costly and if we or any of our CROs fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA, EMA, Health Canada or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to:

- regulators, institutional review boards ("IRBs") or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;

- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;

- our contractors and investigators may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a lack of clinical response or a determination that participants are being exposed to unacceptable health risks;

- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements;

- the cost of clinical trials of our drug candidates may be greater than we anticipate;

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and

- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us, our investigators, or regulators to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;

- not obtain regulatory approval at all;

- obtain approval for indications that are not as broad as intended;

- have a drug removed from the market after obtaining regulatory approval;

- be subject to additional post-marketing testing requirements;

- be subject to restrictions on how a drug is distributed or used; or

- be unable to obtain reimbursement for use of a drug.

Delays in testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Clinical trials may produce negative or inconclusive results. Moreover, these trials may be delayed or proceed less quickly than intended. Delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues and we may not have sufficient funding to complete the testing and approval process. Any of these events may significantly harm our business, financial condition and prospects, lead to the denial of regulatory approval of our drug candidates or allow our competitors to bring drugs to market before we do, impairing our ability to commercialize our drugs if and when approved.

Significant clinical trial delays also could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do, impair our ability to commercialize our drug candidates and may harm our business and results of operations.

We may in the future conduct clinical trials for our drug candidates in sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.

We may in the future conduct certain of our clinical trials outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S. for our New Drug Application ("NDA"), acceptance of this data is subject to certain conditions imposed by the FDA. There can be no assurance the FDA will accept data from any of the clinical trials we conduct outside the U.S. If the FDA does not accept the data from any of our clinical trials conducted outside the U.S., it would likely result in the need for additional clinical trials in the U.S., which would be costly and time-consuming and could delay or prevent the commercialization of any of our drug candidates.

Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

The regulatory approval processes of the FDA, NMPA, EMA, Health Canada and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our current drug candidates or any future drug candidates we may develop, our business will be substantially harmed.

We cannot commercialize drug candidates without first obtaining regulatory approval to market each drug from the FDA, NMPA, EMA, Health Canada or comparable regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in studies in animals and well-controlled clinical trials, and, with respect to approval in the United States and other regulatory agencies, to the satisfaction of the FDA, NMPA, EMA, Health Canada or comparable regulatory authorities, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate.

The time required to obtain approval from the FDA, NMPA, EMA, Health Canada and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of studies in animals and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities.

In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval can differ among regulatory authorities and may change during the course of the development of a drug candidate. We have not obtained regulatory approval for any drug candidate. It is possible that neither our existing drug candidates nor any drug candidates we may discover or acquire for development in the future will ever obtain regulatory approval. Even if we obtain regulatory approval in one jurisdiction, we may not obtain it in other jurisdictions.

Our drug candidates could fail to receive regulatory approval from any of the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities for many reasons, including but not limited to:

- disagreement with regulators regarding the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective or safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with regulators regarding our interpretation of data from studies in animals or clinical trials;
- insufficiency of data collected from clinical trials of our drug candidates to support the submission and filing of a New Drug Application ("NDA"), or other submission or to obtain marketing approval;
- the FDA, NMPA, EMA, Health Canada or a comparable regulatory authority's finding of deficiencies related to the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical studies and clinical data insufficient for approval.

Any of the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities may require more information, including additional preclinical studies or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request. Regulatory authorities also may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that is not desirable for the successful commercialization of that drug candidate. In addition, if our drug candidate produces undesirable side effects or involves other safety issues, the FDA may require the establishment of a Risk Evaluation Mitigation Strategy ("REMS"), or NMPA, EMA, Health Canada or other comparable regulatory authorities may require the establishment of a similar strategy. Such a strategy may, for instance, restrict distribution of our drug candidates, require patient or physician education, or impose other burdensome implementation requirements on us.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our drug candidates if regulatory authorities require additional time or studies to assess the safety or efficacy of our drug candidates.

We currently do not have any drug candidates that have gained approval for sale by the FDA, NMPA or EMA, Health Canada or other regulatory authorities in any other country, and we cannot guarantee that we will ever have marketable drugs. Despite SACT-1 having been granted orphan drug status, this is not an approval for sale by the FDA. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without first obtaining marketing approval from the FDA, NMPA, EMA, Health Canada and comparable regulatory authorities. In the U.S., we hope to file INDs for the drug candidates from our Lead Projects and, subject to the approval of IND, Phase 1 clinical trials in humans. Even if we are permitted to commence such clinical trials, they may not be successful and regulators may not agree with our conclusions regarding the data generated by our clinical trials.

We may be unable to complete development of our drug candidates or initiate or complete development of any future drug candidates we may develop on our projected schedule. While we believe that our existing cash will likely enable us to complete the preclinical development of at least one of our current Lead Projects, the full clinical development, manufacturing and launch of that drug candidate, will take significant additional time and likely require funding beyond the existing cash. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of our drug candidates, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for our drug candidates or any future drug candidates.

Preclinical studies in animals and clinical trials in humans to demonstrate the safety and efficacy of our drug candidates are time-consuming, expensive and take several years or more to complete. Delays in preclinical or clinical trials, regulatory approvals or rejections of applications for regulatory approval in the U.S., Europe, the PRC or other markets may result from many factors, including but not limited to:

- our inability to obtain sufficient funds required to conduct or continue a trial, including lack of funding due to unforeseen costs or other business decisions;
- regulatory reports for additional analysts, reports, data, preclinical studies and clinical trials;
- failure to reach agreement with, or inability to comply with conditions imposed by the FDA, NMPA, EMA, Health Canada or other regulators regarding the scope or design of our clinical trials;
- regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- delay or failure in obtaining authorization to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;
- difficulty in maintaining contact with patients during or after treatment, resulting in incomplete data;
- our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;
- our inability to enroll and retain a sufficient number of patients who meet the inclusion and exclusion criteria in a clinical trial;

- our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical protocols;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, withdrawing from or dropping out of a trial, or becoming ineligible to participate in a trial;
- failure of our clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- manufacturing issues, including problems with manufacturing or timely obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- feedback from the FDA, NMPA, EMA, Health Canada, an IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent studies in animals and clinical trials, regarding our drug candidates, including which might require modification of a trial protocol;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects; and
- a decision by the FDA, NMPA, EMA, Health Canada, an IRB, comparable entities, or the Company, or recommendation by a data safety monitoring board or comparable regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may increase the costs or time required to complete a clinical trial.

If we experience delays in the completion of, or the termination of, a clinical trial, of any of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed. In addition, any delay in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

If we are required to conduct additional clinical trials or other studies with respect to any of our drug candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for that drug candidate, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process. Significant clinical trial delays could allow our competitors to bring their products to market before we do and impair our ability to commercialize our drugs, if and when approved. If any of this occurs, our business will be materially harmed.

Our drug candidates may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events caused by our drug candidates or any future drug candidates we may develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities. Results of our potential clinical trials could reveal a high and unacceptable severity or prevalence of adverse effects. In such event, our trials could be suspended or terminated and the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all target indications. Drug-related adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial, could result in potential product liability claims and may harm our reputation, business, financial condition and business prospects significantly.

Additionally, if any of our current or future drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including but not limited to:

- suspending the marketing of the drug;
- having regulatory authorities withdraw approvals of the drug;
- adding warnings on the label;
- developing a REMS for the drug or, if a REMS is already in place, incorporating additional requirements under the REMS, or to develop a similar strategy as required by a comparable regulatory authority;
- conducting post-market studies;
- being sued and held liable for harm caused to subjects or patients; and
- damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, results of operations and prospects.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If our drug candidates or any future drug candidates we develop are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable regulatory authorities outside of the United States.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements from the FDA, NMPA, EMA, Health Canada and comparable regulatory authorities, including, in the United States, ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug 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 safety and efficacy of the drug candidate. The regulatory authorities may also require risk management plans or programs as a condition of approval of our drug candidates (such as REMS of the FDA and risk-management plan of the EMA), which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, NMPA, EMA, Health Canada or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGCP and cGMP, for any clinical trials that we conduct post-approval.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drug candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our drug candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Companies may promote drugs only for the approved indications and in accordance with the provisions of the approved label and may not promote drugs for any off-label use, such as uses that are not described in the product's labeling and that differ from those approved by the regulatory authorities. However, physicians may prescribe drug products for off-label uses and such off-label uses are common across some medical specialties. Thus, they may, unbeknownst to us, use our product for an "off label" indication for a specific treatment recipient. The FDA, NMPA, EMA, Health Canada and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and if we are found to be out of compliance with the requirements and restrictions imposed on us under those laws and restrictions, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions, and the off-label use of our products may increase the risk of product liability claims. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

The policies of the FDA, NMPA, EMA, Health Canada and other regulatory authorities may change and 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 regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Despite FDA's consent for us to pursue the 505(b)(2) development pathway for SACT-1, we may be unable to successfully complete the 505(b)(2) pathway for the pediatric formulation of SACT-1 to treat neuroblastoma as planned, which would materially impact our likelihood of obtaining FDA approval.

Even though the FDA is allowing us to pursue the 505(b)(2) regulatory pathway for our product candidates, we will need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. We cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

If we or our third-party suppliers fail to comply with the FDA's good manufacturing practice regulations or fail to adequately, timely, or sufficiently respond to an FDA Form 483 or subsequent Warning Letter, this could impair our ability to market our products in a cost-effective and timely manner and could result in FDA enforcement action.

We and our third-party suppliers are required to comply with the FDA's Current Good Manufacturing Practices (cGMP) which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the cGMP and related regulations through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct these inspections or audits at any time. If, during the inspection, FDA identifies issues which, in FDA's judgment, may constitute violations of the Federal Food, Drug, and Cosmetic Act or FDA's regulations, the FDA inspector may issue an FDA Form 483 listing these observations.

Note that if an entity does not address observations found in an FDA Form 483 to FDA's satisfaction, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or recall, detention or seizure of our product;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for pre-market approval of new products;
- withdrawing pre-market approvals that have already been granted;
- refusal to grant export approval for our product; or
- criminal prosecution.

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

Risks Related to Commercialization of Our Drug Candidates

Even if any of our drug candidates receive regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

After we complete clinical trials and receive regulatory approval for any of our drug candidates, which may not happen for some time, we recognize that such candidate(s) may ultimately fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. We may not be able to achieve or maintain market acceptance of our products over time if new products or technology are introduced that are more favorably received than our products, are more cost effective or render our drug obsolete. We will face competition with respect to our drug candidates from other pharmaceutical companies developing products in the same disease/therapeutic area and specialty pharmaceutical and biotechnology companies worldwide. Many of the companies against which we may be competing have significantly greater financial resources and expertise in research and development, manufacturing, animal testing, conducting clinical trials, obtaining regulatory approvals and marketing approval for drugs than we do. Physicians, patients and third-party payors may prefer other novel products to ours, which means that we may not generate significant sales revenues for that product and that product may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- clinical indications for which our drug candidates are approved;
- physicians, hospitals, and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;

- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments and their relative benefits;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- lack of experience and financial and other limitations on our ability to create and sustain effective sales and marketing efforts or ineffectiveness of our sales and marketing partners; and
- changes in legislative and regulatory requirements that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain regulatory approval.

We depend substantially on the success of the drug candidates being researched as our current Lead Projects. If we are unable to license or sublicense, sell or otherwise commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business and the ability to generate revenue related to product sales, if ever achieved, will depend on the successful development, regulatory approval and licensing or sublicensing or other commercialization of our drug candidates or any other drug candidates we may develop. We have invested a significant amount of financial resources in the development of our drug candidates and we may invest in other drug candidates. The success of our drug candidates and any other potential drug candidates will depend on many factors, including but not limited to:

- successful enrollment in, and completion of, studies in animals and clinical trials;
- other parties' ability in conducting our clinical trials safely, efficiently and according to the agreed protocol;
- receipt of regulatory approvals from the FDA, NMPA, EMA, Health Canada and other comparable regulatory authorities for our drug candidates;
- our ability to establish commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- reliance on other parties to conduct our clinical trials swiftly and effectively;
- launch of commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining patents, trade secrets and other IP protection and regulatory exclusivity, as well as protecting our rights in our own IP;
- ensuring that we do not infringe, misappropriate or otherwise violate patents, trade secrets or other IP rights of other parties;
- obtaining acceptance of our drug candidates by doctors and patients;
- obtaining reimbursement from third-party payors for our drug candidates, if and when approved;
- our ability to compete with other drug candidates and drugs; and
- maintenance of an acceptable safety profile for our drug candidates following regulatory approval, if and when received.

We may not achieve regulatory approval and commercialization in a timely manner or at all. Significant delays in obtaining approval for and/or to successfully commercialize our drug candidates would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Risks Related to Our IP

A significant portion of our IP portfolio currently includes pending patent applications that have not yet been issued as granted patents and if the pending patent applications covering our product candidates fail to be issued, our business will be adversely affected. If we or our licensors are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

Our success depends largely on our ability to obtain and maintain patent protection and other forms of IP rights for the composition of matter, method of use and/or method of manufacture for each of our drug candidates. Failure to obtain, maintain protection, enforce or extend adequate patent and other IP rights could materially adversely affect our ability to develop and market one or more of our drug candidates. We also rely on trade secrets and know-how to develop and maintain our proprietary and IP position for each of our drug candidates. Any failure to protect our trade secrets and know-how with respect to any specific drug and diagnostics technology candidate could adversely affect the market potential of that potential product.

As of the date of this report, the Company has, through its licenses, obtained rights to patents and patent applications covering some or all its drug and diagnostics technology candidates that have been filed in major jurisdictions such as the United States, member states of the European Patent Organization (the "EPO") and the PRC (collectively, "Major Patent Jurisdictions"), as well as in other countries. We have also filed a number of provisional applications to establish earlier filing dates for certain of our other ongoing researches, the specifics of which are currently proprietary and confidential. To the extent we do not seek or obtain patent protection in a particular jurisdiction, we may not have commercial incentive to seek marketing authorization in such jurisdiction. Nonetheless, other parties might enter those markets with generic versions or copies of our products and received regulatory approval without having significantly invested in their own research and development costs compared to the Company's investment. For more information about our IP portfolio, please refer to the Intellectual Property section below.

With respect to issued patents in certain jurisdictions, for example in the U.S. and under the EPO, we may be entitled to obtain a patent term extension to extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. We have sought to support our proprietary position by working with our licensors in filing patent applications in the names of the licensors in the United States and through the PCT, related to the Lead Projects and certain other drug candidates. In the future, we intend to file patent applications on supplemental or improvement IP derived from the licensed technologies, where those IP would be solely or jointly owned by the Company pursuant to the terms of respective license agreements. Filing patents covering multiple technologies in multiple countries is time-consuming and expensive, and we may not have the resources file and prosecute all necessary or desirable patent applications in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We cannot be certain that patents will be issued or granted with respect to patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid or unenforceable.

The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the EPO, the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications and even if they do issue, such patents may not issue in a form that effectively prevents others from commercializing competing products. As such, we do not know the degree of future protection that we will have on our proprietary products and technology.

Additionally, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Even if patents do successfully issue and even if such patents cover our drug candidates, other parties may initiate, for patents filed before March 16, 2013 (i.e., the enactment of the America Invents Act), interference or re-examination proceedings, for patents filed on or after March 16, 2013, post-grant review, *inter partes* review, nullification or derivation proceedings, in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Successful defense of its patents can constitute a material factor in a company's expenses. According to an article published by BlueIron (https://finance.yahoo.com/news/current-patent-litigation-costs-between-120200165.html), depending on the value at stake, the American Intellectual Property Law Association's "2019 Report of the Economic Survey" reported the average costs of a patent litigation are between $2.3 million to $4.0 million.

In addition, the fact that the Company has exclusive rights to prevent others from using a patented invention does not necessarily mean that the Company itself will have the unrestricted right to use that invention. Other parties may obtain ownership or licenses to patents or other IP rights that cover the manufacture, use or sale of our current or future products (or elements thereof). This may enable such other parties to enforce their patents or IP rights against us, and may, as a result, affect the commercialization of our products or exploitation of our own technology. We endeavor to identify early patents and patent applications which may block development of a product or technology and minimize this risk by conducting prior art searches before and during the projects. However, relevant documents may be overlooked, yet-to-be published or missed, which may in turn impact on the freedom to commercialize the relevant asset. In such cases, we may not be in a position to develop or commercialize products or drug candidates unless we successfully pursue litigation to nullify or invalidate the other IP rights concerned, or enter into a license agreement with the IP right holder, if available on commercially reasonable terms.

If we are unable to obtain and maintain the appropriate scope for our patents, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

We may not obtain sufficient claim scope in those patents to prevent another party from competing successfully with our drug and diagnostics technology candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technology or drug and diagnostics technology candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug and diagnostics technology candidates, or limit the duration of the patent protection of our technology and drug and diagnostics technology candidates. Given the amount of time required for the development, testing and regulatory review of new drug and diagnostics technology candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug and diagnostics technology candidates similar or identical to ours.

Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' or collaboration partners' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.

We may not be able to protect and enforce our IP rights throughout the world.

Our commercial success will depend, in part, on our ability to maintain IP protection for our drug candidates in which we seek to develop and commercialize. While we rely primarily upon a combination of patents, trademarks, trade secrets and other contractual obligations to protect the IP related to our brands, products and other proprietary technologies, these legal means may afford only limited protection.

Filing and prosecuting patents on drug candidates and defending the validity of the same (if challenged) in all countries throughout the world could be prohibitively expensive for us, and our IP rights in countries outside the Major Patent Jurisdictions can be less extensive than those in the Major Patent Jurisdictions. In addition, the laws of some countries in the rest of the world such as India do not protect IP rights to the same extent as laws in the Major Patent Jurisdictions. Consequently, we may not be able to prevent other parties from practicing our inventions in the rest of the world, despite our continued efforts in enforcing our IP rights through legal means. Competitors may use our technology in jurisdictions where we have not or not yet obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection.

Our, our licensors' or collaboration partners' patent applications cannot be enforced against other parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. In addition, patents and other IP rights also will not protect our technology, drug candidates if another party, including our competitors, design around our protected technology, drug candidates without infringing, misappropriating or otherwise violating our patents or other IP rights.

Moreover, currently and as our R&D continues to progress, some of our patents and patent applications are or may be co-owned with another party. Some of our licenses already provide that future-developed technologies (and any resulting patents) will be co-owned with the licensors and other patents for technologies we may acquire or develop with other parties may also be jointly owned. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other persons, including our competitors, and our competitors could market competing products and technology, and we will be unable to transfer or grant exclusive rights to potential purchasers or development partners of such co-owned technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against other parties, and such cooperation may not be provided to us. Any of the foregoing could limit the revenue we might generate from our patents or patent applications and thus have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors or collaborators were or will be the first to file any patent application related to a drug and diagnostics technology candidate. Furthermore, in the United States, if patent applications of other parties have an effective filing date before March 16, 2013, an interference proceeding can be initiated by such other party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If patent applications of other parties have an effective filing date on or after March 16, 2013, in the United States a derivation proceeding can be initiated by such other parties to determine whether our invention was derived from theirs.

Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, we may be subject to other challenges regarding our exclusive ownership of our IP. If another party were successful in challenging our exclusive ownership of any of our IP, we may lose our right to use such IP, such other party may be able to license such IP to other parties, including our competitors, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Many companies have encountered significant problems in protecting and defending IP rights in jurisdictions outside Major Patent Jurisdictions. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other IP, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other IP rights, or the marketing of competing drugs in violation of our proprietary rights generally.

To date, we have not sought to enforce any issued patents in any jurisdictions. Proceedings to enforce our patent and other IP rights in any jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke other parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate in jurisdictions where opposition proceedings are available and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Certain countries in Europe, the PRC, and developing countries including India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to another party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our IP rights around the world may be inadequate to obtain a significant commercial advantage from the IP that we develop.

We may become involved in lawsuits to protect or enforce our IP, which could be expensive, time-consuming and unsuccessful. Our patent rights relating to our drug and diagnostics technology candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable non-U.S. authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our IP rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our IP rights, to protect our trade secrets or determine the validity and scope of our own IP rights or the proprietary rights of others. This can be expensive and time-consuming. Any claim that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their IP rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their IP rights than we can. Accordingly, despite our efforts, we may not be able to prevent other parties from infringing upon or misappropriating our IP. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent rights or other IP rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent rights or other IP rights do not cover the technology in question. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with IP litigation, there is risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we initiate legal proceedings against another party to enforce our patent, or any patents that may be issued in the future from our patent applications, that relates to one of our drug and diagnostics technology candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which another party can assert invalidity or unenforceability of a patent. Parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug and diagnostics technology candidates. With respect to the validity of our patents, for example, there may be invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug and diagnostics technology candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with IP litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims challenging the inventorship of our patents and other IP.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our IP, we may in the future be subject to claims that former employees, collaborators or other parties have an interest in our patents or other IP as inventors or co-inventors. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug and diagnostics technology candidates and who have not clearly contracted to transfer or assign any rights they may have to the Company. In addition, for our licensed patents, although a majority of our licensors have procured assignment forms and records from inventors to affirm their ownership in the licensed IP, another party or former employee or collaborator of our licensors not named in the patents may challenge the inventorship of claim an ownership interest in one or more of our or our licensors' patents. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose rights such as exclusive ownership of, or right to use, our patent rights or other IP. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are sued for infringing IP rights of other parties, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends in part on our avoiding infringement of the patents and other IP rights of other parties. There is a substantial amount of litigation involving patent and other IP rights in the biotechnology and pharmaceutical industries. Numerous issued patents, provisional patents and pending patent applications, which are owned by other parties, exist in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Other parties may assert that we are employing their proprietary technology without authorization. There may be other patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be currently pending patent applications or provisional patents which may later result in issued patents that our drug candidates may infringe. In addition, other parties may obtain patents in the future and claim that use of our technology infringes upon these patents. If any other patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug candidates, any molecules formed during the manufacturing process or any final drug itself, the holders of any such patents may be able to prevent us from commercializing such drug candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any other patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtain a license, limit our uses, or until such patent expires, or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Other parties who bring successful claims against us for infringement of their IP rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merits, would involve substantial litigation expense and be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement or misappropriation against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from other parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from other parties to advance our research or allow commercialization of our drug candidates. Any required license may not be available at all, or may not be available on commercially reasonable terms. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly reduce our profitability for any product related to that patent and thus harm our business.

Even if resolved in our favor, litigation or other legal proceedings relating to IP claims may cause us to incur significant expenses, and could distract our technical personnel, management personnel, or both from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our Class A Ordinary Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There may be patent applications pending of which we are not aware, but which cover similar products to the ones we are attempting to license or develop, which may result in lost time and money, as well as litigation.

It is possible that we have failed to identify relevant outstanding patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents are issued. Patent applications filed in the United States after November 29, 2000 and generally filed elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or the use of our products. Holders of any such unanticipated patents or patent applications may actively bring infringement claims against us, with the same potential litigation consequences as alluded to elsewhere in this annual report. Any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly submit documents requesting an extension of time. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The terms of our patents may not be sufficient to effectively protect our drug and diagnostics technology candidates and business.

In most countries in which we file, including the United States, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords is limited. For example, depending upon the timing, duration and specifics of the FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, might be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be that of the originally issued patents themselves.

Even if patents covering one of our drug candidates are obtained, thereby giving us a period of exclusivity for manufacturing and marketing that drug, we will not be able to assert such patent rights upon the expiration of the issued patents against potential competitors who may begin marketing generic copies of our medications, and our business and results of operations may be adversely affected.

Changes in patent law in the United States could diminish the value of patents in general, thereby impairing our ability to protect our drug and diagnostics technology candidates.

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents in the United States could change in unpredictable ways that would weaken our ability to obtain new patents, or to enforce our existing patents and patents that we might obtain in the future. For example, in a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other IP rights.

In addition, recent patent reform legislation in the U.S., including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms U.S. patent law in part by changing the U.S. patent system from a "first to invent" system to a "first inventor to file" system, expanding the definition of prior art, and developing a post-grant review system, thus changing the U.S. patent law in a way that may weaken our ability to obtain patent protection in the U.S. for those applications filed after March 16, 2013. Further, the America Invents Act created new procedures to challenge the validity of issued patents in the U.S., including post-grant review and *inter* partes review proceedings, which some other parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by another party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month-period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or other party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by another party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in our loss of the challenged patent right.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our issued patents, provisional patent, and pending patent applications, we expect to rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and protect our drug and diagnostics technology candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If trade secrets which are material to our business were to be obtained by a competitor, our competitive position would be harmed.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed IP, including trade secrets or other proprietary information, of any such employee's former employer. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of IP to execute agreements assigning such IP to us, we may be unsuccessful in executing such an agreement with each party who in fact develops IP that we regard as our own, which may result in claims by or against us related to the ownership of such IP. We are not aware of any threatened or pending claims that any of our projects involve misappropriated IP or other proprietary information, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may be unable to execute on the optimal development plan for one or more of our existing product candidates if we are unable to obtain or maintain necessary rights for some aspect of the developing technology through acquisitions or licenses.

Our existing programs currently use or may in the future use additional technologies subject to proprietary rights held by others, such as particular compositions or methods of manufacture, treatment or use. The licensing and acquisition of IP rights is a competitive area, and more established companies may pursue strategies to license or acquire such IP rights that we may consider necessary or useful. These established companies may have a competitive advantage over us due to their size, cash resources and greater capabilities in clinical development and commercialization.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire IP rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain or maintain licenses or other rights from other parties to use IP of those parties, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license IP rights from other parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

Many of our projects (including our Lead Projects) are based on IP which we have licensed from other parties. (See "Item 4. Information on the Company – B. Business Overview – Intellectual Property") Certain of these license agreements impose diligence, development or commercialization obligations on us, such as obligations to pay royalties on net product sales of our drug candidates once commercialized by us, to pay a percentage of sublicensing revenues if the licensed product is sublicensed, to make other specified milestone and/or annual payments relating to our drug candidates or to pay license maintenance and other fees, as well as obligations to pursue commercialization with due diligence. Specifically, a number of our license agreements also require us to meet development timelines in order to maintain the related license(s). In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore seek to terminate the license agreements. If one of our licensors, despite our efforts, were to be successful in terminating its agreement with us, we would not be able to continue to develop, manufacture or market any drug candidate under that license agreements, and we could face claims for monetary damages or other penalties under that agreement. Such an occurrence would diminish or eliminate the value of that project to our Company, even if we are able to negotiate new or reinstated agreements, which may have less favorable terms. Depending on the importance of the IP and the related project, any such development could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from other parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which (depending on the importance of the IP and the related project) could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement for a project on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug and diagnostics technology candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may not have complete control of the preparation, filing and prosecution of patent applications, or to maintain patents, licensed by us from other parties.

The Company has in-licensed, and may in the future in-license patents owned or controlled by others for our use as part of our development plans. We also may out-license or sublicense patents which we own or control in collaborations with others for development and commercialization of our products. In either case, the continuing right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology under development is a matter for negotiation and we may not always be the party that obtains such control, in which case we will be reliant on our licensors, collaboration partners or sublicensees for determining strategies with respect to those patents. For our existing licenses, while we have an understanding with most of the licensors who maintain control over patent prosecution and we have jointly appointed and engaged patent agents nominated by us under one or more of our licenses, we cannot guarantee that such licensors or collaborators will always accept prosecution strategies proposed by us and/or our patent agents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to establish, maintain or protect such patents and other IP rights, such rights may be reduced or eliminated. If our licensors or joint development partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Risks Related to Our Reliance on Unrelated Parties

We rely on unrelated parties to conduct discovery and further improvement of our innovations and licensed technologies, as well as our preclinical studies and clinical trials. If these unrelated 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 drug candidates, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon CROs and collaborating institutions to monitor and manage data for our ongoing preclinical studies and programs. We rely on these parties for execution of preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, and regulatory requirements and scientific standards, and our reliance on the CROs and collaborating institutions does not relieve us of our regulatory responsibilities. If CROs, collaborating institutions or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, development of our product candidates could be delayed and our business could be adversely affected.

In addition, our CROs and collaborating institutions, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and waste. In the event of contamination or injury resulting from our use of hazardous materials, we might be held liable for any resulting damages, and any liability could exceed our resources. We could also be subject to civil or criminal fines and penalties, and significant associated costs.

If an IND for one of our drug candidates requires significantly larger quantities of the candidate to be tested, we expect to rely on unrelated parties to manufacture supplies of that candidate. If those unrelated parties fail to provide us with sufficient quantities of clinical supply on that candidate or fail to do so at acceptable quality levels or prices, or fail to maintain required cGMP licenses, we may not be able to manufacture that candidate in sufficient quantities to conduct the necessary human trials. Should the failure by the CRO occur in anticipation of or after marketing approval of that candidate, we may be unable to generate as much revenue as rapidly (and such revenue may not be as profitable) as we had anticipated.

The manufacture of many drug products, particularly in commercial quantities, can be complex and may require significant expertise and capital investment, particularly if the development of advanced manufacturing techniques and process controls are required. We intend to contract with outside contractors to manufacture clinical supplies and process our drug candidates. We have not yet had our drug candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our drug candidates.

As we expect to engage contract manufacturers, the Company will be exposed to the following risks:

- we might be unable to identify manufacturers on acceptable terms or at all because the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities must approve any manufacturers we determine to use and any potential manufacturer may be unable to satisfy federal, state or international regulatory standards;

- although we would be choosing manufacturers with the type of experience most suitable for our drug candidates, it is possible that our contract manufacturers may not be able to execute unique manufacturing procedures and other logistical support requirements we have developed and they might require a significant amount of support from us to implement and maintain the infrastructure and processes required to manufacture our particular drug candidates;

- our contract manufacturers might be unable to reproduce the quantity and quality of the drugs we need to meet our clinical and commercial needs within the time frames when we require those drugs;

- our contract manufacturers may breach their contracts with us, including by not performing as agreed or not devoting sufficient resources to our drug candidates, or they may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;

- even if initially accepted by regulatory authorities, a manufacturer remains subject to ongoing periodic unannounced inspection by regulatory authorities to ensure strict compliance with cGMP and other government regulations, and our contract manufacturers may fail to comply with these regulations and requirements, resulting in rescission of cGMP licenses and our inability to continue using their services, requiring us to find a replacement manufacturer;

- depending on the terms of our agreement with a manufacturer, we may not own, or may have to share, the IP rights to any improvements made by the manufacturer in the manufacturing process for our drug candidates; and

- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities, result in higher costs or adversely impact commercialization of our drug candidates.

We are also responsible for quality control by our manufacturers. We intend to rely on those unrelated-party manufactures to perform certain quality assurance tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

Manufacturers of drug products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. It is possible that stability failures or other issues relating to the manufacture of our drug candidates may occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints, or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the manufacturing of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials with additional costs or terminate clinical trials completely.

Review of changes in the manufacturing process of our drug candidates could cause delays resulting from the need for additional regulatory approvals.

Changes in a process or procedure for manufacturing one of our drug candidates, including a change in the location where the drug candidate is manufactured or a change of a contract manufacturer, could require prior review by the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities and approval of the manufacturing process and procedures in accordance with the FDA, NMPA, EMA, or Health Canada's regulations, or comparable requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The new facility will also be subject to pre-approval inspection. In addition, we would have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time-consuming. It is also possible that the FDA, NMPA, EMA, Health Canada or other comparable regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

Risks Related to Our Diagnostics Technology

Our products could in the future be subject to additional regulation by the U.S. Food and Drug Administration or other domestic and international regulatory agencies, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

The FDA has statutory authority to assure that medical devices and in vitro diagnostics, including those where the Paths^{Dx} Test technology may be utilized, are safe and effective for their intended uses. Should the Paths^{Dx} Test technology be utilized in U.S. as a Laboratory Developed Test (LDT), the FDA has historically exercised its enforcement discretion and may not enforce applicable provisions of the FDC Act and regulations with respect to LDTs. We believe the Paths^{Dx} Test may not be subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions.

However, if and when we utilize the Paths^{Dx} Test technology in the U.S., the FDA may disagree with our assessment that the Paths^{Dx} Test falls within the definition of an LDT and seek to regulate the Paths^{Dx} Test as medical devices. If the FDA determines that our products are subject to such requirements, we could be subject to enforcement action, including administrative and judicial sanctions, and additional regulatory controls and submissions for the Paths^{Dx} Test, all of which could be burdensome.

In the future, certain of our products or related applications could be subject to additional FDA regulation. Even where a product is not subject to FDA clearance or approval requirements, the FDA may impose restrictions as to the types of customers to which we can market and sell our products. Such regulation and restrictions may materially and adversely affect our business, financial condition and results of operations. Other regulatory regimes that do not currently present material challenges but that could in the future subject to regulations include biosecurity should our Paths^{Dx} Test technology be utilized in the U.S.

In addition, many countries have laws and regulations that could affect our products and which could limit our ability to sell our products in those countries. The number and scope of these requirements are increasing. We may not be able to obtain regulatory approvals in such countries or may incur significant costs in obtaining or maintaining foreign regulatory approvals. For example, the European Union, or EU, is transitioning from the existing European Directive 98/79/EC on in vitro diagnostic medical devices, or In Vitro Diagnostic Directive (IVDD), to the In Vitro Diagnostic Device Regulation (EU) 2017/746 (IVDR), which imposes stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The IVDR is expected to become effective in May 2022. It is likely that we will be impacted by this new regulation, either directly as a manufacturer of IVDs, or indirectly as a supplier to customers who are placing IVDs in the EU market for clinical or diagnostic use. Complying with the requirements of the IVDR may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations or chemical regulations to the EU requirements.

Risks Related to Our Industry, Business and Operation

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development operations involve the use of hazardous materials, chemicals and various radioactive compounds/radiation. Our R&D Center may maintain quantities of various flammable and toxic chemicals in our facilities that are required for our research, development and manufacturing activities. We are subject to local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials and of medical waste at the jurisdictions where we operate our research facilities, which are currently limited to Hong Kong. We believe our procedures for storing, handling and disposing of these materials comply with the relevant guidelines and laws of the jurisdictions in which our facilities are located. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and medical waste.

We do not maintain workers' compensation insurance or insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties, if we violate any of these laws or regulations.

Our future success depends on our ability to retain our Chief Executive Officer, our scientific and clinical advisors, and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Ian Huen, our Chief Executive Officer, as well as, other principal members of our management teams, scientific teams as well as scientific and clinical advisors. Although we have formal employment agreements, which we refer to as appointment letters, with all of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time, subject to applicable notice periods. Nevertheless, the loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our Company, in addition to salary and cash incentives, we provide share incentive grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the price of our Class A Ordinary Shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have appointment letters with our key employees, any of our employees could resign at any time, with 1-month to 3-months prior written notice or with payment in lieu of notice.

Recruiting and retaining qualified officers, scientific, clinical, sales and marketing personnel or consultants will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical studies development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time, because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drug and diagnostics technology candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

As of the date of this annual report, we have 1 full-time employees. Of these, 1 full-time are engaged in general and administrative functions. As of the date of this annual report, all our employees are located in Asia. In addition, we have engaged and may continue to engage 10 independent contracted consultants and advisors to assist us with our operations. As our development and commercialization plans and strategies develop, and as we have transitioned into operating as a public company, we will need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We will need to add a significant number of additional managerial, operational, sales, marketing, financial and other personnel with the appropriate public company experience and technical knowledge and we may not successfully recruit and maintain such personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including clinical, the FDA or other comparable regulatory authority review process for our drug and diagnostics technology candidates, while complying with our contractual obligations to contractors and others; and
- improving our operational, financial and management controls, reporting systems and procedures.

As we refine our operational strategy to streamline operations, we have adjusted our employment model. The company has shifted from a direct employment approach to outsourcing key functions, including research and development and back-office operations. While this allows for greater focus and flexibility, it also introduces dependencies on third-party vendors, which may present new risks related to quality control, data security, and operational continuity that we are actively managing.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants for significant input in selecting and evaluating new products to pursue. These independent organizations, advisors and consultants may not continue to be available to us on a timely basis when needed, and in such case, we may not have the ability to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities, or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our drug candidates or otherwise advance our business. Furthermore, we may not be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees, outsourcing works or expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug and diagnostics technology candidates and, accordingly, may not achieve our research, development and commercialization goals.

We intend to seek additional collaborations, strategic alliances or acquisitions or enter into royalty-seeking or sublicensing arrangements in the future, but we may not realize the benefits of these arrangements.

We intend to form or seek strategic alliances, create joint ventures or collaborations, acquire complimentary products, IP rights, technology or businesses or enter into additional licensing arrangements with unrelated parties that we determine may complement or augment our development and commercialization efforts with respect to our drug and diagnostics technology candidates. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

We will face significant competition in seeking appropriate strategic partners and the negotiation process is likely to be time-consuming, costly and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or another alternative arrangement for any of our drug and diagnostics technology candidates because their state of development may be deemed to be too early for collaborative effort and others may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy. If and when we enter into an agreement with a collaboration partner or sublicensee for development and commercialization of a drug or diagnostics technology candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the unrelated-party.

Further, even if we enter into a collaboration involving any of our drug and diagnostics technology candidates, the arrangement will be subject to numerous risks, which may include the following:

- the collaborators will likely have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- the collaborator may ultimately choose not pursue development and commercialization of our drug or diagnostics technology candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- the collaborator may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug or diagnostics technology candidate, repeat or conduct new clinical trials, or require a new formulation of a drug or diagnostics technology candidate for clinical testing;
- the collaborator could independently develop, or develop with unrelated parties, drugs that compete directly or indirectly with our drugs or drug candidates;
- the collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;
- the collaborator may not properly maintain or defend our IP rights or may use our IP or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential liability;
- disputes may arise between us and the collaborator that cause the delay or termination of the research, development or commercialization of our drug and diagnostics technology candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- the collaboration may be terminated and, if terminated, may result the Company needing additional capital to pursue further development or commercialization of the applicable drug and diagnostics technology candidates;
- the collaborator may own or co-own IP covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such IP;
- the collaboration may result in increased operating expenses or the assumption of indebtedness or contingent liabilities; and
- the collaboration arrangement may result in the loss of key personnel and uncertainties in our ability to maintain key business relationships.

As a result, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions, which could delay our timelines or otherwise adversely affect our business. Following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with a suitable collaborator on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug or diagnostics technology candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

If we fail to enter into collaborations, we may seek to fund and undertake development or commercialization activities on our own, but we may not have sufficient funds or expertise to undertake the necessary development and commercialization activities. In such a case, we may not be able to further develop our drug and diagnostics technology candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain the FDA approval for any of our drug and diagnostics technology candidates and begin commercializing those drugs in the United States, our potential exposure under U.S. laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators of our sponsored researches and research patients and our use of information obtained in the course of patient recruitment for clinical trials, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

We believe that any disclosure controls and procedures, or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of our Class A Ordinary Shares. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating results. In connection with the audit of our financial statements for the year ended December 31, 2024, we and our independent registered public accounting firm identified one material weakness in our internal control over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board of the United States. The material weakness identified was the lack of dedicated resources to take responsibility for the finance and accounting functions and the preparation of financial statements in compliance with generally accepted accounting principles in the United States, or U.S. GAAP.

We have took actions to remediate the abovementioned material weakness:

- provide trainings to staff regarding to the preparation of financial statements in compliance with generally accepted accounting principles in the United States;
- change to a new and well-established accounting system to enhance effectiveness and financial and system control;
- establish clear roles and responsibilities for accounting and financial reporting staff to address finance and accounting issues; and
- continue to monitor the improvement on internal control over financial reporting.

However, since we are still in the process of replenishing and building up a qualified finance and accounting team with sufficient dedicated resources, our management assessed that the deficiency related to the lack of dedicated resources to take responsibility for the finance and accounting functions and the preparation of financial statements in compliance with generally accepted accounting principles in the United States, or U.S. GAAP, still existed as of December 31, 2024. We cannot assure you that we will not identify additional material weaknesses or significant deficiencies in the future.

Our management concluded that our internal controls over financial reporting were not effective as of December 31, 2024. Investors may lose confidence in our operating results, the price of the Class A Ordinary Shares 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 of the Sarbanes-Oxley Act, the Class A Ordinary Shares may not be able to remain listed on the NASDAQ Capital Market.

We may market our products, if approved, globally; if we do, we will be subject to the risk of doing business internationally.

We operate and expect to operate in various countries, and we may not be able to market our products in, or develop new products successfully for, these markets. We may also encounter other risks of doing business internationally including but not limited to:

- unexpected changes in, or impositions of, legislative or regulatory requirements;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- differences in protection of our IP rights including patent rights of other parties;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships, which could affect, among other things, customers' inventory levels and consumer purchasing, which could cause our results to fluctuate and our net sales to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations.

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 may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, IP rights, technology or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increase in operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, IP and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic 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 and diagnostics technology candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If we fail to comply with the U.S. Foreign Corrupt Practices Act ("FCPA"), or other anti-bribery laws, including the Bribery Act 2010 of the United Kingdom (UK Bribery Act"), our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the FCPA. The FCPA and UK Bribery Act generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business or other benefits. We are also subject to the anti-bribery laws of other jurisdictions, particularly the PRC. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

Our business and results of operations may be negatively impacted by the UK's withdrawal from the EU.

On June 23, 2016, the UK held a referendum in which a majority of voters approved an exit from the EU, or Brexit, and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most part with EU regulations, however it is possible that these regimes will diverge in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the EU on January 31, 2022, and provides for a streamlined clinical trial application and assessment procedure covering multiple EU Member States has not been implemented into UK law, and a separate application will need to be submitted for clinical trial authorization in the UK. In addition, as we are headquartered in the UK, it is possible that Brexit may impact some or all of our current operations. For example, Brexit will impact our ability to freely move employees from our headquarters in the UK to other locations in the EU. Furthermore, if other EU Member States pursue withdrawal, barrier-free access among the EEA overall could be diminished or eliminated.

The long-term effects of Brexit will depend in part on how the terms of the TCA continue to take effect in practice and the terms of any further agreements the UK makes with the EU. Such a withdrawal from the EU is unprecedented, and it is unclear how the restrictions on the UK's access to the European single market for goods, capital, services and labor, or single market, and the wider commercial, legal and regulatory environment, will impact our future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK in the long term.

If we commence clinical trials of one of our drug or diagnostics technology candidates, and product liability lawsuits are brought against us, we may incur substantial liabilities and the commercialization of such drug or diagnostics technology candidates may be affected.

If any of our drug or diagnostics technology candidates enter clinical trials, we will face an inherent risk of product liability suits and will face an even greater risk if we obtain approval to commercialize any drugs. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drugs;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in the price of our Class A Ordinary Shares.

We shall seek to obtain the appropriate insurance once our candidates are ready for clinical trial. However, our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with collaborators. We currently do not have in place product liability insurance and although we plan to have in place such insurance as and when the products are ready for commercialization, as well as insurance covering clinical trials, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may 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. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Additionally, we may be sued if the products that we commercialize, market or sell cause or are perceived to cause injury or are found to be otherwise unsuitable, and may result in:

- decreased demand for those products;
- damage to our reputation;
- costs incurred related to product recalls;
- limiting our opportunities to enter into future commercial partnership; and
- a decline in the price of our Class A Ordinary Shares.

Our insurance coverage may be inadequate to protect us against losses.

We currently maintain property insurance for our office premises. We hold employer's liability insurance generally covering death or work-related injury of employees; we maintain company insurance for those persons working in our offices and medical insurance for our certain employee. We hold public liability insurance covering certain incidents involving unrelated parties that occur on or in the premises of the Company. We have directors and officers liability insurance. We do not have key-man life insurance on any of our senior management or key personnel, or business interruption insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. If any claims for damage are brought against us, or if we experience any business disruption, litigation or natural disaster, we might incur substantial costs and diversion of resources.

Fluctuations in exchange rates could result in foreign currency exchange losses

Our operations and equity are funded in U.S. dollars and we currently incur the majority of our expenses in U.S. dollars or in H.K. dollars. H.K. dollar is currently pegged to the U.S. dollar; however, we cannot guarantee that such peg will continue to be in place in the future. Our exposure to foreign exchange risk primarily relates to the limited cash denominated in currencies other than the functional currencies of each entity and limited revenue contracts dominated in H.K. dollars in certain Hong Kong operating entities. We do not believe that we currently have any significant direct foreign exchange risk and have not hedged exposures denominated in foreign currencies or any other derivative financial instruments.

If we are exposed to foreign currency exchange risk as our results of operations, cash flows maybe subject to fluctuations in foreign currency exchange rates. For example, if a significant portion of our clinical trial activities may be conducted outside of the United States, and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs. Foreign currency fluctuations are unpredictable and may adversely affect our financial condition, results of operations and cash flows.

Our investments are subject to risks that could result in losses.

We had cash and cash equivalents of $0.88 million, $2.01 million, and $1.88 million as of December 31, 2024, 2023, and 2022, respectively. We may invest our cash in a variety of financial instruments. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. While we believe our cash position does not expose us to excessive risk, future investments may be subject to adverse changes in market value.

We are exposed to risks associated with our computer hardware, network security and data storage.

Similar to all other computer network users, our computer network system is vulnerable to attack of computer virus, worms, trojan horses, hackers or other similar computer network disruptive problems. Any failure in safeguarding our computer network system from these disruptive problems may cause breakdown of our computer network system and leakage of confidential information of the Company. Any failure in the protection of our computer network system from external threat may disrupt our operation and may damage our reputation for any breach of confidentiality to our customers, which in turn may adversely affect our business operation and performance. In the event that our confidential information is stolen and misused, we may become exposed to potential risks of losses from litigation and possible liability.

In addition, we are highly dependent on our IT infrastructure to store research data and information and manage our business operations. We do not backup all data on a real-time basis and the effectiveness of our business operations may be materially affected by any failure in our IT infrastructure. If our communications and IT systems do not function properly, or if there is any partial or complete failure of our systems, we could suffer financial losses, business disruption or damage to our reputation.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject to supply chain disruptions, earthquakes, power shortages, telecommunications failures, damage from computer viruses, material computer system failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. In addition, we partially rely on our research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on contract manufacturers to produce and process our drug candidates. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. A large portion of our contract manufacturer's operations is in a single facility. Damage or extended periods of interruption to our corporate or our contract manufacturer's development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our drug candidates.

We may be exposed to various risks related to the regulatory environment of the pharmaceutical industry in the PRC.

We are the exclusive licensee to certain PRC patents directed to our drug candidates; and we also intend to file application for certain products in the PRC. The pharmaceutical industry in the PRC is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. (See "Item 4. Information on the Company – B. Business Overview – Regulations"). In recent years, the regulatory framework in the PRC regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in the PRC and reduce the current benefits that we believe are available to us from developing and manufacturing drugs in the PRC. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in the PRC. We believe our strategy and approach is aligned with the PRC government's policies, but we cannot ensure that our strategy and approach will continue to be aligned.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies. Our financial condition and results of operation in the PRC could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us and consequently have a material adverse effect on our businesses, financial condition and results of operations.

If the U.S. Public Company Accounting Oversight Board, or the PCAOB, is unable to inspect our auditors as required under the Holding Foreign Companies Accountable Act, the SEC will prohibit the trading of our Class A Ordinary Shares. A trading prohibition for our Class A Ordinary Shares, or the threat of a trading prohibition, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections of our auditors would deprive our investors of the benefits of such inspections.

On March 24, 2021, the SEC adopted interim final rules relating to the implementation of certain disclosure and documentation requirements of the HFCAA. An identified issuer will be required to comply with these rules if the SEC identifies it as having a "non-inspection" year under a process to be subsequently established by the SEC. On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act, and on December 29, 2022, legislation entitled "Consolidated Appropriations Act, 2023" (the "Consolidated Appropriations Act") was signed into law by President Biden, which contained, among other things, an identical provision to the Accelerating Holding Foreign Companies Accountable Act and amended the HFCAA by requiring the SEC to prohibit an issuer's securities from trading on any U.S stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three, thus reducing the time period for triggering the prohibition on trading. If our auditor cannot be inspected by the Public Company Accounting Oversight Board, or the PCAOB, for two consecutive years, the trading of our securities on any U.S. national securities exchanges, as well as any over-the-counter trading in the U.S., will be prohibited. On September 22, 2021, the PCAOB adopted a final rule implementing the HFCAA, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCAA, whether the PCAOB is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction. On December 2, 2021, the SEC issued amendments to finalize rules implementing the submission and disclosure requirements in the HFCAA. The rules apply to registrants that the SEC identifies as having filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that PCAOB is unable to inspect or investigate completely because of a position taken by an authority in foreign jurisdictions. On December 16, 2021, the PCAOB issued a report on its determinations that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and in Hong Kong, because of positions taken by PRC authorities in those jurisdictions, which determinations were vacated on December 15, 2022.

On August 26, 2022, the PCAOB announced that it had signed a Statement of Protocol (the "SOP") with the China Securities Regulatory Commission and the Ministry of Finance of China. The SOP, together with two protocol agreements governing inspections and investigations (together, the "SOP Agreement"), establishes a specific, accountable framework to make possible complete inspections and investigations by the PCAOB of audit firms based in mainland China and Hong Kong, as required under U.S. law.

On December 15, 2022, the PCAOB announced that it was able to secure complete access to inspect and investigate PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong completely in 2022. The PCAOB Board vacated its previous 2021 determinations that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong. However, whether the PCAOB will continue to be able to satisfactorily conduct inspections of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong is subject to uncertainties and depends on a number of factors out of our and our auditor's control. The PCAOB continues to demand complete access in mainland China and Hong Kong moving forward and is making plans to resume regular inspections in early 2023 and beyond, as well as to continue pursuing ongoing investigations and initiate new investigations as needed. The PCAOB has also indicated that it will act immediately to consider the need to issue new determinations with the HFCAA if needed.

Our current independent accounting firm, Marcum Asia CPAs LLP, whose audit report is included in this annual report on Form 20-F, is headquartered in Manhattan, New York, and was not included in the list of PCAOB Identified Firms in the PCAOB December 2021 Release. It has been inspected by the PCAOB on a regular basis with the last inspection in 2023. Our ability to retain an auditor subject to PCAOB inspection and investigation, including but not limited to inspection of the audit working papers related to us, may depend on the relevant positions of U.S. and Chinese regulators. With respect to audits of companies with operations in China or Hong Kong, such as the Company, there are uncertainties about the ability of our auditor to fully cooperate with a request by the PCAOB for audit working papers in China or Hong Kong without the approval of Chinese authorities. If in the future Marcum Asia CPAs LLP is included in the list of PCAOB Identified Firms and we are unable to retain a PCAOB-registered auditor subject to PCAOB inspection and investigation, a trading prohibition for our Class A Ordinary Shares could be issued shortly after our filing of the second consecutive annual report on Form 20-F for which we have retained a PCAOB Identified Firm.

If our Class A Ordinary Shares are subject to a trading prohibition under the HFCA Act, the price of our Class A Ordinary Shares may be adversely affected, and the threat of such a trading prohibition would also adversely affect their price. If we are unable to be listed on another securities exchange that provides sufficient liquidity, such a trading prohibition may substantially impair your ability to sell or purchase our Class A Ordinary Shares when you wish to do so. Furthermore, if we are able to maintain a listing of our Class A Ordinary Shares on a non-U.S. exchange, investors owning our Class A Ordinary Shares may have to take additional steps to engage in transactions on that exchange, including establishing non-U.S. brokerage accounts.

The HFCA Act also imposes additional certification and disclosure requirements for Commission Identified Issuers, and these requirements apply to issuers in the year following their listing as Commission Identified Issuers. The additional requirements include a certification that the issuer is not owned or controlled by a governmental entity in the Relevant Jurisdiction, and the additional requirements for annual reports include disclosure that the issuer's financials were audited by a firm not subject to PCAOB inspection, disclosure on governmental entities in the Relevant Jurisdiction's ownership in and controlling financial interest in the issuer, the names of Chinese Communist Party, or CCP, members on the board of the issuer or its operating entities, and whether the issuer's article's include a charter of the CCP, including the text of such charter.

The SEC could take the position that we are an "investment company" subject to the extensive requirements of the Investment Company Act of 1940. Such a characterization and the associated compliance requirements could have a material adverse effect on our business, financial condition, and results of operations.

Our business had historically included passive healthcare related investments in early stage companies primarily in the United States. Although we are in the process of liquidating those securities that remain in our portfolio, we still hold some such investments and these are included as assets of our Company on a consolidated basis. As part of the Restructure, we resolved to exit such portfolio investments over an appropriate timeframe and focus our resources on our current business. Since the date of the Restructure, we have not held ourselves out as an investment company and we do not believe we are an "investment company" under the Investment Company Act of 1940. If the SEC or a court, however, were to disagree with us, we could be required to register as an investment company. This would subject us to disclosure and accounting rules geared toward investment companies, rather than operating companies, which may limit our ability to borrow money, issue options, issue multiple classes of stock and debt, and engage in transactions with affiliates, and may require us to undertake significant costs and expenses to meet the disclosure and regulatory requirements to which we would be subject as a registered investment company.

If we are classified as a passive foreign investment company for U.S. federal income tax purposes, United States holders of our Class A Ordinary Shares may be subject to adverse United States federal income tax consequences.

A non-U.S. corporation will be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes, for such year, if either

- At least 75% of its gross income for such year is passive income; or
- The average percentage of our assets (determined at the end of each quarter) during such year which produce passive income or which are held for the production of passive income is at least 50%.

Passive income generally includes dividends, interests, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets.

A separate determination must be made after the close of each taxable year as to whether a non-U.S. corporation is a PFIC for that year. For purposes of the PFIC analysis, in general, a non-U.S. corporation is deemed to own its pro rata share of the gross income and assets of any entity in which it is considered to own at least 25% of the equity by value. Based on the current and anticipated value of our assets, we believe we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2024, and we may be a PFIC for U.S. federal income tax purposes for our current taxable year ending December 31, 2025.

In determining whether we are a PFIC, cash and cash equivalents and investments are considered by the U.S. Internal Revenue Service ("IRS") to be a passive asset. During our taxable year ended December 31, 2024, we believe that the amount of cash we had on hand and investments were greater than 50% of our total assets. The composition of our assets during the current taxable year may cause us to continue to be classified as a PFIC. The determination of whether we will be a PFIC for our current taxable year or a future year may depend in part upon how quickly we spend our liquid assets, and on the value of our goodwill and other unbooked intangibles not reflected on our balance sheet, which may depend upon the market value of our Class A Ordinary Shares from time to time. Further, while we will endeavor to use a classification methodology and valuation approach that is reasonable, the IRS may challenge our classification or valuation of our goodwill and other unbooked intangibles for purposes of determining whether we are a PFIC in the current or one or more future taxable years.

If we are a PFIC for any taxable year during which a U.S. Holder owns our Class A Ordinary Shares or warrants, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. As discussed under "Taxation – Material U.S. Federal Income Tax Considerations for U.S. Holders – Passive Foreign Investment Company Rules", a U.S. Holder may be able to make certain tax elections that would lessen the adverse impact of PFIC status; however, in order to make such elections the U.S. holder will usually have to have been provided information about the company by us, and there is no assurance that the company will provide such information.

For a more detailed discussion of the application of the PFIC rules to us and the consequences to U.S. holders if we were determined to be a PFIC. (See "Item 10. Additional Information – E. Taxation – Material U.S. Federal Income Tax Considerations for U.S. Holders – Passive Foreign Investment Company Rules")

Our results of operation may be negatively affected should the 2019-nCov virus (Coronavirus) continue to spread on a wider scale.

Our business could be adversely affected by the effects of a widespread outbreak of contagious disease, including the outbreak of respiratory illness caused by a novel coronavirus. Any outbreak of contagious diseases, and other adverse public health developments, particularly in China, could have a material and adverse effect on our business operations. These could include disruptions or restrictions on our ability to travel or to distribute our products, as well as temporary closures of our facilities or the facilities of our suppliers or customers.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in various countries, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns, undergo the compulsory universal testing by the HKSAR Government or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

In addition, the trading prices for our Class A Ordinary Shares and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our securities or such sales may be on unfavorable terms.

The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our preclinical studies and clinical trials.

As a result of the COVID-19 outbreak, or similar pandemics, we have and may in the future experience disruptions that could materially and adversely impact our manufacturing, preclinical development activities, preclinical studies and planned clinical trial. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials, should the relevant clinical trials be approved;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines for regulatory submission and trial initiation;
- interruption or delays in our CROs and collaborators meeting expected deadlines or complying with regulatory requirements related to preclinical development activities, preclinical studies and planned clinical trials;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling or clinical trial application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions and “shelter in place” orders;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

Risks Related to Our Corporate Structure

One of our directors controls a majority of our voting shares.

One of our Executive Directors and CEO, Mr. Ian Huen, and his affiliates, over which he is deemed to have control and/or have substantial influence, has voting rights with respect to an aggregate of 3,506,391 Ordinary Shares, on an as converted basis (1,900,244 Class A Ordinary Shares and 1,606,147 Class B Ordinary Shares), representing approximately 87% of the voting power of our outstanding ordinary shares as of the date hereof. As a result, Mr. Huen has the ability to control the outcome of matters submitted to our shareholders for approval, including the election of directors and any merger, consolidation, or sale of all or substantially all of our assets. Additionally, in the event that Mr. Huen controls our company at the time of his death, control may be transferred to a person or entity that he designates as his successor. As a board member, Mr. Huen owes a fiduciary duty to our shareholders and must act in good faith in a manner he reasonably believes to be in the best interests of our shareholders. As a shareholder, even a controlling shareholder, Mr. Huen is entitled to vote his shares, and shares over which he has voting control as a result of voting agreements, in his own interests, which may not always be in the interests of our shareholders generally.

As a "controlled company" under the rules of the NASDAQ Capital Market, we may choose to exempt our company from certain corporate governance requirements that could have an adverse effect on our public shareholders.

Our directors and officers beneficially own a majority of the voting power of our outstanding Ordinary Shares. Under the Rule 4350(c) of the NASDAQ Capital Market, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirement that a majority of our directors be independent, as defined in the NASDAQ Capital Market Rules, and the requirement that our compensation and nominating and corporate governance committees consist entirely of independent directors. Although we do not intend to rely on the "controlled company" exemption under the Nasdaq listing rules, we could elect to rely on this exemption in the future. If we elect to rely on the "controlled company" exemption, a majority of the members of our board of directors might not be independent directors and our nominating and corporate governance and compensation committees might not consist entirely of independent directors. Accordingly, during any time while we remain a controlled company relying on the exemption and during any transition period following a time when we are no longer a controlled company, you would not have the same protections afforded to shareholders of companies that are subject to all of the NASDAQ Capital Market corporate governance requirements. Our status as a controlled company could cause our Class A Ordinary Share to look less attractive to certain investors or otherwise harm our trading price.

We may not be able to consolidate the financial results of some of our affiliated companies or such consolidation could materially adversely affect our operating results and financial condition.

The Company has one VIE which is incorporated under the laws of Cayman Islands and conducts operations in Hong Kong. The Company does not currently consolidate this VIE since the Group does not have a variable interest in them and is not determined to be the primary beneficiary of it at this time under U.S. GAAP. This determination is based on whether the Group has a variable interest (or combination of variable interests) that provides the Company with (a) the power to direct the activities that most significantly impact the VIE's economic performance and (b) the obligation to absorb losses or right to receive benefits that could be potentially significant to the VIE. The Group continually reassesses whether it is the primary beneficiary of a VIE throughout the entire period the Group is involved with the VIE. According to those standards, we determined that we do not have the power to manage and make decisions that affect Libra's research and development activities, which activities most significantly impact Libra's economic performance. Accordingly, we determined that we are not the primary beneficiary of Libra. As a result, Libra's financial results are not consolidated in our consolidated financial statements. If, in the future an affiliate company becomes a VIE and we become the primary beneficiary of it for accounting purposes, we would be required to consolidate that entity's financial results in our consolidated financial statements. If we become the primary beneficiary of Libra and have to consolidate them into our consolidated financial statements, Libra and such entity's financial results were negative, this could have a corresponding negative impact on our operating results.

The economic substance legislation of the Cayman Islands may adversely impact us or our operations.

The Company is subject to Cayman Islands economic substance legislation ("ESA") requiring that where the Company carries on a relevant activity (as defined in the ESA) it must maintain economic substance within the Cayman Islands, including adequate premises and employees within the Cayman Islands. As an entity subject to the ESA, the Company is required to assess its operations to determine the required compliance (if any) with the ESA, to file an annual notification with the Cayman Islands Registrar of Companies disclosing whether the Company is carrying out any relevant activities within the meaning of the ESA and an annual return with the Department of International Tax Co-Operation. Where applicable, the Company must establish that its operations satisfy the economic substance requirements of the ESA. The Company is required to monitor its operations to ensure it remains in compliance with all requirements under the ESA. Failure to satisfy these requirements may subject the Company to penalties under the ESA.

Risks Related to our Securities

If we fail to comply with the continued listing requirements of NASDAQ, we would face possible delisting, which would result in a limited public market for our shares and make obtaining future debt or equity financing more difficult for us.

On February 8, 2023, the Company received a deficiency letter from the Nasdaq Listing Qualifications Department (the "**Staff**") of the Nasdaq Stock Market LLC ("**Nasdaq**") notifying the Company that the Company does not meet the minimum Market Value of Publicly Held Shares ("**MVPHS**") of $5,000,000 for the previous 30 consecutive business days. The Nasdaq deficiency letter has no immediate effect on the listing of the Company's Class A Ordinary Shares, and its Class A Ordinary Shares will continue to trade on The Nasdaq Global Market under the symbol "APM" at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(D), the Company has been given 180 calendar days, or until August 7, 2023, to regain compliance with Rule 5450(b)(1)(C). If at any time before August 7, 2023, the MVPHS closes at $5,000,000 or more for a *minimum* of ten consecutive business days, the Staff will provide written confirmation that the Company has achieved compliance and the matter will be closed.

If the Company does not regain compliance with Rule 5450(b)(1)(C) by August 7, 2023, the Company will receive written notification that its securities are subject to delisting and the Company may appeal the delisting determination to a Hearing's Panel. Alternatively, the Company may consider applying to transfer the Class A Ordinary Shares to The Nasdaq Capital Market. The Company intends to remain on the Nasdaq Global Market and will actively monitor its MVPHS and will consider available options to resolve the deficiency and regain compliance with Rule 5450(b)(1)(C).

On July 31, 2023, the Company requested to transfer its Class A Ordinary Shares from the Nasdaq Global Market to the Nasdaq Capital Market. On August 8, 2023, the Company received an approval letter (the "Nasdaq Approval Letter") from the Nasdaq Listing Qualifications Department indicating that the staff has approved the Company's application to transfer its Class A Ordinary Shares to the Nasdaq Capital Market. The Company's securities have been transferred to the Nasdaq Capital Market at the opening of business on August 10, 2023, and the trading activities of its Class A Ordinary Shares have not been affected. The transfer became effective on August 10, 2023, thereby closing the prior deficiencies on the Nasdaq Global Market.

On April 15, 2025, the Company received a notification from the Staff advising the Company that it did not comply with the minimum bid price requirement of $1 per share, as per Nasdaq Listing Rule 5550(a)(2). The notification does not immediately affect the listing or trading of the Company's shares on Nasdaq. The Company has been granted a 180-calendar-day grace period, until 14 October 2025, to regain compliance with the continued listing requirements. There is no guarantee that the Company will achieve the minimum bid price and regain compliance with the specified rule.

If the Company fails to regain compliance with this rule or any other listing rules when required in the future, we could be subject to suspension and delisting proceedings. If our securities lose their status on the Nasdaq Capital Market, our securities would likely trade in the over-the-counter market. If our securities were to trade on the over-the-counter market, selling our securities could be more difficult because smaller quantities of securities would likely be bought and sold, transactions could be delayed, and security analysts' coverage of us may be reduced. In addition, in the event our securities are delisted, broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in our securities, further limiting the liquidity of our securities. These factors could result in lower prices and larger spreads in the bid and ask prices for our securities. Such delisting from the NASDAQ Capital Market and continued or further declines in our share price could also greatly impair our ability to raise additional necessary capital through equity or debt financing, and could significantly increase the ownership dilution to shareholders caused by our issuing equity in financing or other transactions.

Class A Ordinary Shares eligible for future sale may adversely affect the market price of our Class A Ordinary Shares if the shares are successfully listed on NASDAQ or other stock markets, as the future sale of a substantial amount of outstanding Class A Ordinary Shares in the public marketplace could reduce the price of our Class A Ordinary Shares.

The market price of our Class A Ordinary Shares could decline as a result of sales of substantial amounts of our Class A Ordinary Shares in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of our Class A Ordinary Shares. An aggregate of 5,346,823 Class A Ordinary Shares are outstanding as of the issuance date of this annual report. 4,950,322 of the Class A Ordinary Shares are freely transferable without restriction or further registration under the Securities Act. The remaining Class A Ordinary Shares will be "restricted securities" as defined in Rule 144. These Class A Ordinary Shares may be sold without registration under the Securities Act to the extent permitted by Rule 144 or other exemptions under the Securities Act.

A sale or perceived sale of a substantial number of our Ordinary Shares may cause the price of our Class A Ordinary Shares to decline.

If our shareholders sell substantial amounts of our Class A Ordinary Shares in the public market, the market price of our Class A Ordinary Shares could fall. Moreover, the perceived risk of this potential dilution could cause shareholders to attempt to sell their shares and investors to short our Class A Ordinary Shares. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Issuances by us of additional securities, could affect ownership and voting rights over us. In addition, the issuance of preferred shares, or options or warrants to purchase those preferred shares, could negatively impact the value of the Ordinary Shares as the result of preferential dividend rights, conversion rights, redemption rights and liquidation provisions granted to the stockholders of such preferred shares.

From time to time, we may issue in public or private sales additional securities to third party investors. Such securities may provide holders with ownership and voting rights that could provide the holders thereof with substantial influence over our business. Any preferred shares that may be issued shall have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. There cannot be any assurance that we will not issue preferred securities with rights and preferences that are more beneficial than those provided to our Ordinary Shares.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our shares.

We have never paid any cash dividends on our Class A Ordinary Shares and do not anticipate paying any cash dividends on our Class A Ordinary Shares in the foreseeable future, and any return on investment may be limited to the value of our Class A Ordinary Shares. We plan to retain any future earnings to finance growth.

Our dividend policy is subject to the discretion of our Board of Directors and will depend on, among other things, our earnings, financial condition, capital requirements and other factors. There is no assurance that our Board of Directors will declare dividends even if we are profitable. Under Cayman Islands law, dividends may be declared and paid only out of funds legally available therefor, namely out of either profit or our share premium account, and provided further that a dividend may not be paid if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business and the realizable value of assets of our Company will not be less than the sum of our total liabilities, other than deferred taxes as shown on our books of account, and our capital.

Our Class B Ordinary Shares have greater voting power than our Class A Ordinary Shares and certain existing shareholders have substantial influence over our Company and their interests may not be aligned with the interests of our other shareholders.

We have a dual-class voting structure consisting of Class A Ordinary Shares and Class B Ordinary Shares. Under this structure, holders of Class A Ordinary Shares are entitled to one vote per share, and holders of Class B Ordinary Shares are entitled to one hundred votes per share, which can cause the holders of Class B Ordinary Shares to have an unbalanced, higher concentration of voting power. Our management team as a group beneficially owns over 1.6 million Class B Ordinary Shares representing approximately 87% voting power. As a result, until such time as their collective voting power is below 50%, our management team as a group of controlling shareholders have substantial influence over our business, including decisions regarding mergers, consolidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions. They may take actions that are not in the best interests of us or our other shareholders. These corporate actions may be taken even if they are opposed by our other shareholders. Further, concentration of ownership of our Class B Ordinary Shares may discourage, prevent or delay the consummation of change of control transactions that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their shares. Future issuances of Class B Ordinary Shares may also be dilutive to the holders of Class A Ordinary Shares. As a result, the market price of our Class A Ordinary Shares could be adversely affected.

Shareholders who hold shares of Class B Ordinary Shares, including our executive officers and their affiliates, hold approximately 97% of the voting power of our outstanding ordinary shares. Because of the one hundred-to-one voting ratio between our Class B Ordinary Shares and Class A Ordinary Shares, the holders of our Class B Ordinary Shares will collectively continue to control a majority of the combined voting power of our Ordinary Shares and therefore be able to control all matters submitted to our shareholders for approval, so long as the Class B Ordinary Shares represent at least 1.0% of all outstanding shares of our Ordinary Shares.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technology or drug and diagnostics technology candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Class A Ordinary Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations, and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license IP rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Class A Ordinary Shares to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to another party on unfavorable terms our rights to technology or drug and diagnostics technology candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Since we are a Cayman Islands exempted company, the rights of our shareholders may be more limited than those of shareholders of a company organized in the United States.

Our corporate affairs are governed by our Third Amended and Restated Memorandum and Articles of Association (as may be amended from time to time) ("Memorandum and Articles"), the Companies Act (As Revised) of the Cayman Islands (the "Companies Law") and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. Under the laws of some jurisdictions in the United States, majority and controlling shareholders generally have certain fiduciary responsibilities to the minority shareholders. Shareholder action must be taken in good faith, and actions by controlling shareholders which are obviously unreasonable may be declared null and void. Cayman Islands law protecting the interests of minority shareholders may not be as protective in all circumstances as the law protecting minority shareholders in some U.S. jurisdictions. In addition, the circumstances in which a shareholder of a Cayman Islands company may sue the company derivatively, and the procedures and defenses that may be available to the company, may result in the rights of shareholders of a Cayman Islands company being more limited than those of shareholders of a company organized in the United States. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing has occurred. The Cayman Islands courts are also unlikely to recognize or enforce judgments from U.S. courts based on certain liability provisions of U.S. securities laws that are penal in nature. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, although the courts of the Cayman Islands will generally recognize and enforce non-penal judgment of a foreign court of competent jurisdiction for a liquidated sum without retrial on its merits which is not obtained in a manner contrary to public policy in the Cayman Islands and in respect of which there are no concurrent proceedings in the Cayman Islands. This means, even if shareholders were to sue us successfully, they may not be able to recover anything to make up for the losses suffered.

Furthermore, our directors have the power to take certain actions without shareholder approval which would require shareholder approval under the laws of most U.S. jurisdictions. For example, the directors of a Cayman Islands company, without shareholder approval, may implement a sale of any assets, property, part of the business, or securities of the Company.

While Cayman Islands law allows a dissenting shareholder to express the shareholder's view that a court sanctioned reorganization of a Cayman Islands company would not provide fair value for the shareholder's shares, Cayman Islands statutory law does not specifically provide for shareholder appraisal rights on a merger or consolidation of a company. This may make it more difficult for you to assess the value of any consideration you may receive in a merger or consolidation or to require that the acquirer gives you additional consideration if you believe the consideration offered is insufficient. However, Cayman Islands' statutory law does provide a mechanism for a dissenting shareholder in a merger or consolidation to apply to the Grand Court for a determination of the fair value of the dissenter's shares, if it is not possible for the Company and the dissenter to agree a fair price within the time limits prescribed.

Shareholders of Cayman Islands exempted companies, such as our Company, have no general rights under Cayman Islands' law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have discretion under our Memorandum and Articles to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Lastly, under the law of the Cayman Islands, there is little statutory law for the protection of minority shareholders. The principal protection under statutory law is that shareholders may bring an action to enforce the constituent documents of the corporation, our Memorandum and Articles. Shareholders are entitled to have the affairs of the company conducted in accordance with the general law and the memorandum and articles of association.

There are common law rights for the protection of shareholders that may be invoked, largely dependent on English company law, since the common law of the Cayman Islands for business companies is limited. Under the general rule pursuant to English company law known as the rule in Foss v. Harbottle, a court will generally refuse to interfere with the management of a company at the insistence of a minority of its shareholders who express dissatisfaction with the conduct of the company's affairs by the majority or the board of directors. However, every shareholder is entitled to have the affairs of the company conducted properly according to law and the constituent documents of the company. As such, if those who control the company have persistently disregarded the requirements of company law or the provisions of the company's memorandum and articles of association, then the courts will grant relief. Generally, the areas in which the courts will intervene are the following: (1) an act complained of which is outside the scope of the authorized business or is illegal or not capable of ratification by the majority; (2) acts that constitute fraud on the minority where the wrongdoers control the company; (3) acts that infringe on the personal rights of the shareholders, such as the right to vote; and (4) where the company has not complied with provisions requiring approval of a special or extraordinary majority of shareholders, which are more limited than the rights afforded minority shareholders under the laws of many states in the United States subject to limited exceptions, under Cayman Islands Law a minority shareholder may not bring a derivative action against directors. Our Cayman Islands' counsel has advised us that they are aware of one recent as yet unreported derivative action having been brought in a Cayman Islands' court. Class actions are not recognized in the Cayman Islands, but groups of shareholders with identical interests may bring representative proceedings, which are similar.

As a result, you may be limited in your ability to protect your interests if you are harmed in a manner that would otherwise enable you to sue in a United States federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in U.S. federal courts.

As a result of all of the above, shareholders of our Company may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would have as shareholders of a public U.S. company.

You may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited because we are incorporated under Cayman Islands law, we currently conduct substantially all of our operations outside the United States and some of our directors and executive officers reside outside the United States.

We are incorporated in the Cayman Islands and currently conduct substantially all of our operations outside the United States through our subsidiaries. Some of our directors and executive officers reside outside the United States and a substantial portion of their assets are located outside of the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the Cayman Islands, the United Kingdom or in Hong Kong, in the event that you believe that your rights have been infringed under the securities laws of the United States or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands, the United Kingdom and Hong Kong may render you unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, the United Kingdom or Hong Kong, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits if such judgment is final, for a liquidated sum, not in the nature of taxes, a fine or penalty, is not inconsistent with a Cayman Islands' judgment in respect of the same matters, and was not obtained in a manner which is contrary to public policy. In addition, a Cayman Islands court may stay proceedings if concurrent proceedings are being brought elsewhere.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the NASDAQ Capital Market corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer, we are permitted to take advantage of certain provisions in the NASDAQ Capital Market listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. We may follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the NASDAQ Capital Market in respect of the following. For instance, Cayman law does not require that we obtain shareholder approval to issue 20% or more of our outstanding Ordinary Shares in a private offering nor we make our interim results available to shareholders, although as a NASDAQ listed company we are required to publicly file interim results for the first six months of our fiscal year. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

Our auditor has expressed substantial doubt about our ability to continue as a going concern. We may be unable to obtain additional capital on favorable terms.

As a result of recurring net losses and limited cash reserves, our independent auditor has included a going concern paragraph to its report on our financial statements as of and for the fiscal years ended December 31, 2024, due to the substantial doubt that exists in our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and to achieve sustainable revenues and profitable operations. Since inception, we have raised funds primarily through the sale of equity securities and the issuance of debt. We will need and are currently seeking additional funds to operate our business and the recent volatility of global capital markets has made the raising of capital by equity and debt financing more difficult. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations or cause substantial dilution for our stockholders. If we are unable to obtain additional funds, our ability to carry out and implement our planned business objectives and strategies will be significantly delayed, limited, or may not occur. We cannot guarantee that we will become profitable. Even if we achieve profitability, given the competitive and evolving nature of the industry in which we operate, we may not be able to sustain or increase profitability and our failure to do so would adversely affect our business, including our ability to raise additional funds.

Risks Related to Doing Business in Hong Kong

Our company currently does not have operations in mainland China. Accordingly, the laws and regulations of the PRC do not currently have any material impact on our business, financial condition and results of operations. However, if certain PRC laws and regulations were to become applicable to a company such as us in the future, the application of such laws and regulations may have a material adverse impact on our business, financial condition and results of operations and our ability to offer or continue to offer securities to investors, any of which may cause the value of our Class A Ordinary Shares, to significantly decline or become worthless. See the following risk factors of "Our business, financial condition and results of operations, and/or the value of our Class A Ordinary Shares or our ability to offer or continue to offer securities to investors may be materially and adversely affected to the extent the laws and regulations of the PRC become applicable to a company such as us" and "The PRC government exerts substantial influence and discretion over the manner in which companies incorporated under the laws of PRC must conduct their business activities. If we were to become subject to such direct influence or discretion, it may result in a material change in our operations and/or the value of your Class A Ordinary Shares, which would materially affect the interests of investors."

Political risks associated with conducting business in Hong Kong.

Most of our operations are based in Hong Kong. Accordingly, our business operations and financial conditions will be affected by the political and legal developments in Hong Kong. During the period covered by the financial information incorporated by reference into and included in this Report, we maintain substantially most of our operations in Hong Kong. Any adverse economic, social and/or political conditions, material social unrest, strike, riot, civil disturbance or disobedience, as well as significant natural disasters, may affect the market may adversely affect the business operations of our operations. Hong Kong is a special administrative region of the PRC and the basic policies of the PRC regarding Hong Kong are reflected in the Basic Law (the "Hong Kong Basic Law" or the "Basic Law"), namely, Hong Kong's constitutional document, which provides Hong Kong with a high degree of autonomy and executive, legislative and independent judicial powers, including that of final adjudication under the principle of "one country, two systems". However, there is no assurance that there will not be any changes in the economic, political and legal environment in Hong Kong in the future. Since our operation is based in Hong Kong, any change of such political arrangements may pose immediate threat to the stability of the economy in Hong Kong, thereby directly and adversely affecting our results of operations and financial positions.

Under the Basic Law of the Hong Kong Special Administrative Region of the People's Republic of China, Hong Kong is exclusively in charge of its internal affairs and external relations, while the government of the PRC is responsible for its foreign affairs and defense. As a separate customs territory, Hong Kong maintains and develops relations with foreign states and regions. Based on certain recent development including the Law of the People's Republic of China on Safeguarding National Security in the Hong Kong Special Administrative Region issued by the Standing Committee of the PRC National People's Congress in June 2020, the U.S. State Department has indicated that the United States no longer considers Hong Kong to have significant autonomy from China and Former President Trump signed an executive order and Hong Kong Autonomy Act ("HKAA") to remove Hong Kong's preferential trade status and to authorize the U.S. administration to impose blocking sanctions against individuals and entities who are determined to have materially contributed to the erosion of Hong Kong's autonomy. The United States may impose the same tariffs and other trade restrictions on exports from Hong Kong that it places on goods from mainland China. These and other recent actions may represent an escalation in political and trade tensions involving the U.S., China and Hong Kong, which could potentially harm our business.

Given the relatively small geographical size of Hong Kong, any of such incidents may have a widespread effect on our business operations, which could in turn adversely and materially affect our business, results of operations and financial condition. It is difficult to predict the full impact of the HKAA on Hong Kong and companies with operations in Hong Kong like us. Furthermore, legislative or administrative actions in respect of China-U.S. relations could cause investor uncertainty for affected issuers, including us, and the market price of our Ordinary Shares could be adversely affected.

If we become directly subject to the recent scrutiny, criticism and negative publicity involving U.S.-listed Chinese companies, we may have to expend significant resources to investigate and resolve the matter which could harm our business operations, stock price and reputation and could result in a loss of your investment in our stock, especially if such matter cannot be addressed and resolved favorably.

Recently, U.S. public companies that have substantially all of their operations in China, including Hong Kong, have been the subject of intense scrutiny, criticism and negative publicity by investors, financial commentators and regulatory agencies, such as the SEC. Much of the scrutiny, criticism and negative publicity has centered around financial and accounting irregularities and mistakes, a lack of effective internal controls over financial accounting, inadequate corporate governance policies or a lack of adherence thereto and, in many cases, allegations of fraud. As a result of the scrutiny, criticism and negative publicity, the publicly traded stock of many U.S. listed Chinese companies has sharply decreased in value and, in some cases, has become virtually worthless. Many of these companies are now subject to shareholder lawsuits and SEC enforcement actions and are conducting internal and external investigations into the allegations. It is not clear what effect this sector-wide scrutiny, criticism and negative publicity will have on our company, our business and our stock price. If we become the subject of any unfavorable allegations, whether such allegations are proven to be true or untrue, we will have to expend significant resources to investigate such allegations and/or defend our company. This situation will be costly and time consuming and distract our management from growing our company.

The recent joint statement by the SEC, proposed rule changes submitted by Nasdaq, and an act passed by the U.S. Senate and the U.S. House of Representatives, all call for additional and more stringent criteria to be applied to emerging market companies. These developments could add uncertainties to our offering, business operations, share price and reputation.

U.S. public companies that have substantially all of their operations in China and Hong Kong have been the subject of intense scrutiny, criticism and negative publicity by investors, financial commentators and regulatory agencies, such as the SEC. Much of the scrutiny, criticism and negative publicity has centered on financial and accounting irregularities and mistakes, a lack of effective internal controls over financial accounting, inadequate corporate governance policies or a lack of adherence thereto and, in many cases, allegations of fraud.

On April 21, 2020, SEC Chairman Jay Clayton and PCAOB Chairman William D. Duhnke III, along with other senior SEC staff, released a joint statement highlighting the risks associated with investing in companies based in or have substantial operations in emerging markets including China, including Hong Kong, reiterating past SEC and PCAOB statements on matters including the difficulty associated with inspecting accounting firms and audit work papers in China and Hong Kong and higher risks of fraud in emerging markets and the difficulty of bringing and enforcing SEC, Department of Justice and other U.S. regulatory actions, including in instances of fraud, in emerging markets generally.

On May 20, 2020, the U.S. Senate passed the HFCA Act requiring a foreign company to certify it is not owned or controlled by a foreign government if the PCAOB is unable to audit specified reports because the company uses a foreign auditor not subject to PCAOB inspection. If the PCAOB is unable to inspect the company's auditors for three consecutive years, the issuer's securities are prohibited to trade on a national exchange. On December 2, 2020, the U.S. House of Representatives approved the HFCA Act.

On May 21, 2021, Nasdaq filed three proposals with the SEC to (i) apply minimum offering size requirement for companies primarily operating in a "Restrictive Market", (ii) prohibit Restrictive Market companies from directly listing on Nasdaq Capital Market, and only permit them to list on Nasdaq Global Select or Nasdaq Global Market in connection with a direct listing and (iii) apply additional and more stringent criteria to an applicant or listed company based on the qualifications of the company's auditors.

On March 24, 2021, the SEC announced the adoption of interim final amendments to implement the submission and disclosure requirements of the HFCA Act. In the announcement, the SEC clarifies that before any issuer will have to comply with the interim final amendments, the SEC must implement a process for identifying covered issuers. The announcement also states that the SEC staff is actively assessing how best to implement the other requirements of the HFCA Act, including the identification process and the trading prohibition requirements.

On June 22, 2021, the U.S. Senate passed the AHFCAA, which, if signed into law, would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to the PCAOB inspections for two consecutive years instead of three consecutive years.

On September 22, 2021, the PCAOB adopted a final rule implementing the HFCA Act, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCA Act, whether the board of directors of a company is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction.

On December 2, 2021, the SEC adopted amendments to finalize rules implementing the submission and disclosure requirements in the HFCA Act.

On December 16, 2021, the PCAOB issued a report on its determinations that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and in Hong Kong because of positions taken by PRC and Hong Kong authorities in those jurisdictions.

On December 29, 2022, the Consolidated Appropriations Act was signed into law by President Biden. The Consolidated Appropriations Act contained, among other things, an identical provision to AHFCAA, which reduce the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three years to two.

The lack of access to the PCAOB inspection in China prevents the PCAOB from fully evaluating audits and quality control procedures of the auditors based in China. As a result, investors may be deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of these accounting firm's audit procedures or quality control procedures as compared to auditors outside of China that are subject to the PCAOB inspections, which could cause investors and potential investors in our Class A Ordinary Shares to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

Our auditor, Marcum Asia CPAs LLP, as the auditor of companies that are traded publicly in the U.S. and registered with the PCAOB, are subject to laws in the U.S., pursuant to which the PCAOB conducts regular inspections to assess their compliance with the applicable professional standards. Marcum Asia CPAs LLP is headquartered in Manhattan, New York, and have been inspected by the PCAOB on a regular basis, and Marcum Asia CPAs LLP is not subject to the determinations announced by the PCAOB on December 16, 2021.

However, the recent developments would add uncertainties to our ability to offer or continue to offer securities and we cannot assure you whether the national securities exchange we apply to for listing or regulatory authorities would apply additional and more stringent criteria to us after considering the effectiveness of our auditor's audit procedures and quality control procedures, adequacy of personnel and training, or sufficiency of resources, geographic reach, or experience as it relates to our audit. In addition, the HFCA Act, as amended, which requires that the PCAOB be permitted to inspect an issuer's public accounting firm within two years, may result in the delisting of our Company or prohibition of trading in our Class A Ordinary Shares in the future if the PCAOB is unable to inspect our accounting firm at such future time.

On August 26, 2022, the China Securities Regulatory Commission, the MOF, and the PCAOB signed the Protocol governing inspections and investigations of audit firms based in mainland China and Hong Kong, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. Pursuant to the fact sheet with respect to the Protocol disclosed by the SEC, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation and has the unfettered ability to transfer information to the SEC. On December 15, 2022, the PCAOB Board determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and voted to vacate its previous determinations to the contrary. However, should PRC authorities obstruct or otherwise fail to facilitate the PCAOB's access in the future, the PCAOB Board will consider the need to issue a new determination.

As a result of this scrutiny, criticism and negative publicity, the publicly traded stock of many U.S. listed Chinese and Hong Kong companies sharply decreased in value and, in some cases, has become virtually worthless. Many of these companies are now subject to shareholder lawsuits and SEC enforcement actions and are conducting internal and external investigations into the allegations. It is not clear what effect this sector-wide scrutiny, criticism and negative publicity will have on us, our ability to offer or continue to offer securities, business and our share price. If we become the subject of any unfavorable allegations, whether such allegations are proven to be true or untrue, we will have to expend significant resources to investigate such allegations and/or defend our company. This situation will be costly and time consuming and distract our management from developing our growth. If such allegations are not proven to be groundless, we and our business operations will be severely affected and you could sustain a significant decline in the value of our share.

Nasdaq may apply additional and more stringent criteria for our continued listing because our insiders hold a large portion of our listed securities.

Nasdaq Listing Rule 5101 provides Nasdaq with broad discretionary authority over the initial and continued listing of securities in Nasdaq and Nasdaq may use such discretion to deny initial listing, apply additional or more stringent criteria for the initial or continued listing of particular securities, or suspend or delist particular securities based on any event, condition, or circumstance that exists or occurs that makes initial or continued listing of the securities on Nasdaq inadvisable or unwarranted in the opinion of Nasdaq, even though the securities meet all enumerated criteria for initial or continued listing on Nasdaq. In addition, Nasdaq has used its discretion to deny initial or continued listing or to apply additional and more stringent criteria in the instances, including but not limited to: (i) where the company engaged an auditor that has not been subject to an inspection by PCAOB, an auditor that PCAOB cannot inspect, or an auditor that has not demonstrated sufficient resources, geographic reach, or experience to adequately perform the company's audit; (ii) where the company planned a small public offering, which would result in insiders holding a large portion of the company's listed securities; and (iii) where the company did not demonstrate sufficient nexus to the U.S. capital market, including having no U.S. shareholders, operations, or members of the board of directors or management. The insiders of our Company hold a large portion of the company's listed securities. Therefore, we may be subject to the additional and more stringent criteria of Nasdaq for our continued listing, which might result in deficiency letters or inquiries that will take management's time away from focusing on our operations.

Our business, financial condition and results of operations, and/or the value of our Class A Ordinary Shares or our ability to offer or continue to offer securities to investors may be materially and adversely affected to the extent the laws and regulations of the PRC become applicable to a company such as us.

We currently do not have or intend to have any subsidiary or any contractual arrangement to establish a variable interest entity structure with any entity in mainland China. All of our operating entities are in jurisdictions outside of mainland China, including all two of our VIEs which are incorporated under the laws of Cayman Islands and conduct operations in Hong Kong. However, as our principal place of business is in Hong Kong, a special administrative region of China, there is no guarantee that if certain existing or future laws of the PRC become applicable to a company such as us, it will not have a material adverse impact on our business, financial condition and results of operations and/or our ability to offer or continue to offer securities to investors, any of which may cause the value of such securities to significantly decline or be worthless.

Except for the Basic Law, the national laws of the PRC do not apply in Hong Kong unless they are listed in Annex III of the Basic Law and applied locally by promulgation or local legislation. National laws that may be listed in Annex III are currently limited under the Basic Law to those which fall within the scope of defense and foreign affairs as well as other matters outside the limits of the autonomy of Hong Kong. National laws and regulations relating to data protection, cybersecurity and anti-monopoly have not been listed in Annex III and so do not apply directly to Hong Kong.

The laws and regulations in the PRC are evolving, and their enactment timetable, interpretation and implementation involve significant uncertainties. To the extent any PRC laws and regulations become applicable to us, we may be subject to the risks and uncertainties associated with the legal system in the PRC, including with respect to the enforcement of laws and the possibility of changes of rules and regulations with little or no advance notice. We currently do not have plan to expand our operation or acquire any operation in the mainland China. However, we may also become subject to the laws and regulations of the PRC to the extent we commence business and customer facing operations in mainland China as a result of any future acquisition, expansion or organic growth.

The PRC government exerts substantial influence and discretion over the manner in which companies incorporated under the laws of PRC must conduct their business activities. If we were to become subject to such direct influence or discretion, it may result in a material change in our operations and/or the value of our Class A Ordinary Shares, which would materially affect the interest of the investors.

The PRC legal system is evolving rapidly and the PRC laws, regulations, and rules may change quickly with little advance notice. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the non-precedential nature of these decisions, the interpretation of these laws, rules and regulations may contain inconsistences, the enforcement of which involves uncertainties. The PRC government has exercised and continues to exercise substantial control over many sectors of the PRC economy through regulation and/or state ownership. Government actions have had, and may continue to have, a significant effect on economic conditions in the PRC and businesses which are subject to such government actions.

We have business operations in Hong Kong, but not in mainland China, and we directly, or indirectly via our subsidiaries, own equity interests in our operating entities, none of which are located in mainland China, although all three of our VIEs are incorporated under the laws of Cayman Islands and conduct operations in Hong Kong. Our principal executive offices are located in Europe, but our principal place of business is in Hong Kong, a special administrative region of China. The PRC government currently does not exert direct influence and discretion over the manner in which we conduct our business activities outside of mainland China, however, there is no guarantee that we will not be subject to such direct influence or discretion in the future due to changes in laws or other unforeseeable reasons or as a result of our future expansion or acquisition of operations in mainland China. See "- Our business, financial condition and results of operations, and/or the value of our Class A Ordinary Shares or our ability to offer or continue to offer securities to investors may be materially and adversely affected to the extent the laws and regulations of the PRC become applicable to a company such as us."

We currently do not have plans to expand our operation or acquire any operation in the mainland China. However, if we were to become subject to the direct intervention or influence of the PRC government at any time due to changes in laws or other unforeseeable reasons or as a result of our future development, expansion or acquisition of operations in the PRC, it may require a material change in our operations and/or result in increased costs necessary to comply with existing and newly adopted laws and regulations or penalties for any failure to comply. In addition, the market prices of our Class A Ordinary Shares could be adversely affected as a result of anticipated negative impacts of any such government actions, as well as negative investor sentiment towards Hong Kong-based companies subject to direct PRC government oversight and regulation, regardless of our actual operating performance. There can be no assurance that the Chinese government would not intervene in or influence our operations at any time.

We were not required to obtain permission from the PRC government to list on a U.S. securities exchange, however there is no guarantee that this will continue to be the case in the future in relation to the continued listing of our securities on a securities exchange outside of the PRC, or even when such permission is obtained, it will not be subsequently denied or rescinded. Any actions by the PRC government to exert more oversight and control over offerings (including of businesses whose primary operations are in Hong Kong) that are conducted overseas and/or foreign investments in Hong Kong-based issuers could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of our securities, including our Class A Ordinary Shares, to significantly decline or be worthless.

The enactment of Law of the PRC on Safeguarding National Security in the Hong Kong Special Administrative Region (the "Hong Kong National Security Law") could impact our Hong Kong holding subsidiary.

On June 30, 2020, the Standing Committee of the PRC National People's Congress adopted the Hong Kong National Security Law. This law defines the duties and government bodies of the Hong Kong National Security Law for safeguarding national security and four categories of offences - secession, subversion, terrorist activities, and collusion with a foreign country or external elements to endanger national security - and their corresponding penalties. On July 14, 2020, the former U.S. President Donald Trump signed the Hong Kong Autonomy Act, or HKAA, into law, authorizing the U.S. administration to impose blocking sanctions against individuals and entities who are determined to have materially contributed to the erosion of Hong Kong's autonomy. On August 7, 2020 the U.S. government imposed HKAA-authorized sanctions on eleven individuals, including former HKSAR chief executive Carrie Lam. On October 14, 2020, the U.S. State Department submitted to relevant committees of Congress the report required under HKAA, identifying persons materially contributing to "the failure of the Government of China to meet its obligations under the Joint Declaration or the Basic Law." The HKAA further authorizes secondary sanctions, including the imposition of blocking sanctions, against foreign financial institutions that knowingly conduct a significant transaction with foreign persons sanctioned under this authority. The imposition of sanctions may directly affect the foreign financial institutions as well as any third parties or customers dealing with any foreign financial institution that is targeted. It is difficult to predict the full impact of the Hong Kong National Security Law and HKAA on Hong Kong and companies located in Hong Kong. If our Hong Kong subsidiaries are determined to be in violation of the Hong Kong National Security Law or the HKAA by competent authorities, our business operations, financial position and results of operations could be materially and adversely affected.

The Hong Kong legal system embodies uncertainties which could limit the availability of legal protections.

As one of the conditions for the handover of the sovereignty of Hong Kong to China, China accepted conditions such as Hong Kong's Basic Law. The Basic Law ensured Hong Kong will retain its own currency (Hong Kong Dollar), legal system, parliamentary system and people's rights and freedom for fifty years from 1997. This agreement has given Hong Kong the freedom to function with a high degree of autonomy. The Special Administrative Region of Hong Kong is responsible for its own domestic affairs including, but not limited to, the judiciary and courts of last resort, immigration and customs, public finance, currencies and extradition. Hong Kong continues using the English common law system.

However, if the PRC attempts to alter its agreement to allow Hong Kong to function autonomously, this could potentially impact Hong Kong's common law legal system and may in turn bring about uncertainty in, for example, the enforcement of our contractual rights. This could, in turn, materially and adversely affect our business and operations. Additionally, intellectual property rights and confidentiality protections in Hong Kong may not be as effective as in the United States or other countries. Accordingly, we cannot predict the effect of future developments in the Hong Kong legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. These uncertainties could limit the legal protections available to us, including our ability to enforce our agreements with our customers.

There remain some uncertainties as to whether we will be required to obtain approvals from Chinese authorities to list on the U.S. exchanges and offer or continue to offer securities in the future, and if required, we cannot assure you that we will be able to obtain such approval.

The Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (the "M&A Rules"), adopted by six PRC regulatory agencies in 2006 and amended in 2009, requires an overseas special purpose vehicle formed for listing purposes through acquisitions of PRC domestic companies and controlled by PRC companies or individuals to obtain the approval of the China Securities Regulatory Commission ("CSRC") prior to the listing and trading of such special purpose vehicle's securities on an overseas stock exchange.

We are also aware that recently, the PRC government initiated a series of regulatory actions and statements to regulate business operations in certain areas in mainland China with little advance notice, including cracking down on illegal activities in the securities market, enhancing supervision over mainland-China-based companies listed overseas using variable interest entity structure, adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement. For example, on July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to crack down on illegal activities in the securities market and promote the high-quality development of the capital market, which, among other things, requires the relevant governmental authorities to strengthen cross-border oversight of law-enforcement and judicial cooperation, to enhance supervision over mainland-China-based companies listed overseas, and to establish and improve the system of extraterritorial application of the PRC securities laws.

On December 28, 2021, the Cyberspace Administration of China ("CAC"), and other PRC authorities promulgated the Cybersecurity Review Measures, which took effect on February 15, 2022. In addition, the Cybersecurity Law, which was adopted by the Standing Committee of the National People's Congress on November 7, 2016 and came into force on June 1, 2017, and the Cybersecurity Review Measures, or the "Review Measures", provide that personal information and important data collected and generated by a critical information infrastructure operator in the course of its operations in mainland China must be stored in mainland China, and if a critical information infrastructure operator purchases internet products and services that affect or may affect national security, it should be subject to national security review by the CAC together with competent departments of the State Council. In addition, for critical information infrastructure operators, or the "CIIOs", that purchase network-related products and services, the CIIOs shall declare any network-related product or service that affects or may affect national security to the Office of Cybersecurity Review of the CAC for cybersecurity review. Due to the lack of further interpretations, the exact scope of what constitutes a "CIIO" remains unclear. Further, the PRC government authorities may have wide discretion in the interpretation and enforcement of these laws. In addition, the Review Measures stipulates that any online platform operators holding more than one million users/users' individual information shall be subject to cybersecurity review before listing abroad. As of the date of the annual report, neither we nor our subsidiaries have received any notice from any authorities identifying us or our subsidiaries as a CIIO or requiring us or our subsidiaries to undertake a cybersecurity review by the CAC. Further, as of the date of the annual report, neither we nor our subsidiaries have been subject to any penalties, fines, suspensions, or investigations from any competent authorities for violation of the regulations or policies that the CAC has issued.

On June 10, 2021, the Standing Committee of the National People's Congress promulgated the Data Security Law, which took effect on September 1, 2021. The Data Security Law requires that data shall not be collected by theft or other illegal means, and it also provides for a data classification and hierarchical protection system. The data classification and hierarchical protection system protects data according to its importance in economic and social development, and the damages it may cause to national security, public interests, or the legitimate rights and interests of individuals and organizations if the data is falsified, damaged, disclosed, illegally obtained or illegally used, which protection system is expected to be built by the state for data security in the near future. On November 14, 2021, CAC published the Regulations on the Data Security Administration Draft, or the "Data Security Regulations Draft", to solicit public opinion and comments. Under the Data Security Regulations Draft, an overseas initial public offering to be conducted by a data processor processing the personal information of more than one million individuals shall apply for a cybersecurity review. Data processor means an individual or organization that independently makes decisions on the purpose and manner of processing in data processing activities, and data processing activities refers to activities such as the collection, retention, use, processing, transmission, provision, disclosure, or deletion of data. Currently we do not expect the Review Measures to have an impact on the business and operations of our Hong Kong subsidiaries, because (i) our Hong Kong subsidiaries are incorporated and operating in Hong Kong without any subsidiary or variety interest entity ("VIE") structure in mainland China, and it is unclear whether the Review Measures shall be applied to a Hong Kong company; (ii) as of the date of the annual report, our Hong Kong subsidiaries have not collected or stored personal information of any individual clients of mainland China; and (iii) as of the date of this annual report, our Hong Kong subsidiaries have not been informed by any PRC governmental authority of any requirement that it file for a cybersecurity review for the offering. Based on laws and regulations currently in effect in the PRC as of the date of this annual report, we believe our Hong Kong subsidiaries are not required to pass the cybersecurity review of the CAC in order to list our Class A Ordinary Shares in the U.S.

In addition, on February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines, which came into effect on March 31, 2023. Pursuant to the Trial Measures, domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete filing procedures with the CSRC pursuant to the requirements of the Trial Measures within three working days following its submission of initial public offerings or listing application. If a PRC company fails to complete required filing procedures or conceals any material fact or falsifies any major content in its filing documents, such PRC company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines. In addition, on February 24, 2023, the CSRC, together with Ministry of Finance of the PRC, National Administration of State Secrets Protection and National Archives Administration of China, revised the Provisions on Strengthening Confidentiality and Archives Administration for Overseas Securities Offering and Listing which was issued by the CSRC, National Administration of State Secrets Protection and National Archives Administration of China in 2009, or the Provisions. The revised Provisions is issued under the title the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies, and came into effect on March 31, 2023, together with the Trial Measures. One of the major revisions to the revised Provisions is expanding its application to cover indirect overseas offering and listing, as is consistent with the Trial Measures. The revised Provisions require that, including but not limited to (a) a domestic company that plans to, either directly or indirectly through its overseas listed entity, publicly disclose or provide to relevant individuals or entities including securities companies, securities service providers and overseas regulators, any documents and materials that contain state secrets or working secrets of government agencies, shall first obtain approval from competent authorities according to law, and file with the secrecy administrative department at the same level; and (b) domestic company that plans to, either directly or indirectly through its overseas listed entity, publicly disclose or provide to relevant individuals and entities including securities companies, securities service providers and overseas regulators, any other documents and materials that, if leaked, will be detrimental to national security or public interest, shall strictly fulfill relevant procedures stipulated by applicable national regulations. As of the date of this annual report, we have not received any formal inquiry, notice, warning, sanction, or objection from the CSRC with respect to the listing of our Class A Ordinary Shares. However, there remains significant uncertainty as to the enactment, interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities. If it is determined that we are subject to the Trial Measures for the listing of the Ordinary Shares on the Nasdaq, we may fail to obtain required approval, complete required filing or meet such requirements in a timely manner or at all, or completion could be rescinded. Any failure or perceived failure of us to fully comply with such new regulatory requirements could significantly limit or completely hinder our ability to offer or continue to offer securities to investors, cause significant disruption to our business operations, and severely damage our reputation, which could materially and adversely affect our financial condition and results of operations and could cause the value of our securities to significantly decline or be worthless.

If we are determined to be subject to the Draft Rules Regarding Overseas Listings, we cannot assure you that we will be able to receive clearance of such filing requirements in a timely manner, or at all, even though we believe that none of the situations that would clearly prohibit overseas listing and offering applies to us. Based on laws and regulations currently in effect in the PRC as of the date of this annual report, we believe our Hong Kong subsidiaries are not required to obtain regulatory approval from the CSRC in order to list our Class A Ordinary Shares in the U.S.

Since these proposed rules, statements and regulatory actions are new, it is highly uncertain how soon the legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any. Any failure of us to fully comply with new regulatory requirements may significantly limit or completely hinder our ability to offer or continue to offer the Class A Ordinary Shares, cause significant disruption to our business operations, severely damage our reputation, materially and adversely affect our financial condition and results of operations, and cause the Class A Ordinary Shares to significantly decline in value or become worthless.

As of the date of this annual report, we believe are not required to obtain approvals from the PRC authorities to operate our business or list on the U.S. exchanges and offer or continue to offer securities; specifically, we are currently not required to obtain any permission or approval from the CSRC, the CAC or any other PRC governmental authority to operate our business or to list our securities on a U.S. securities exchange or issue securities to foreign investors. However, if we and our Hong Kong subsidiaries (i) do not receive or maintain such approval, should the approval be required in the future by the PRC government, (ii) inadvertently conclude that such approval is not required, or (iii) applicable laws, regulations, or interpretations change and we are required to obtain such approval in the future, our operations and financial condition could be materially adversely affected, and our ability to offer or continue to offer securities to investors could be significantly limited or completely hindered and the securities currently being offered may substantially decline in value and become worthless.

Nevertheless, since these statements and regulatory actions are new, it is highly uncertain how soon the legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any. It is also highly uncertain what potential impact such modified or new laws and regulations will have on Aptorum Group's daily business operations, our ability to accept foreign investments and the listing of our Class A Ordinary Shares on a U.S. or other foreign exchanges. If there is significant change to current political arrangements between mainland China and Hong Kong, the PRC government intervenes or influences operations of companies operated in Hong Kong like us, or exerts more control through change of laws and regulations over offerings conducted overseas and/or foreign investment in issuers like us, it may result in a material change in our operations and/or the value of the securities we are registering for sale or could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of our Class A Ordinary Shares to significantly decline or become worthless.

It may be difficult for overseas shareholders and/or regulators to conduct investigations or collect evidence within China.

Shareholder claims or regulatory investigations that are common in the United States generally are difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of mutual and practical cooperation mechanisms. Furthermore, according to Article 177 of the PRC Securities Law, or Article 177, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC. While detailed interpretation of or implementation rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase difficulties faced by you in protecting your interests.

Our auditor's audit working papers are located in PRC. In the event that the U.S. regulators carry out investigation on us and there is a need to conduct investigation or collect evidence within the territory of the PRC, the U.S. regulators may not be able to carry out such investigation or evidence collection directly in the PRC under the PRC laws. The U.S. regulators may consider cross-border cooperation with securities regulatory authority of the PRC by way of judicial assistance, diplomatic channels or regulatory cooperation mechanism established with the securities regulatory authority of the PRC.

We have ceased to qualify as an "emerging growth company" and will incur increased costs as a result.

We ceased to be an "emerging growth company" on December 31, 2023. Accordingly, we are no longer eligible for reduced disclosure requirements and exemptions available to EGCs and, among other things, will formally become subject to new accounting pronouncement effective dates for non-EGCs. While we have determined that we are neither an accelerated filer nor a large accelerated filer (as such terms are defined under U.S. federal securities laws) and therefore not required to obtain an attestation report from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, we nevertheless expect to incur additional legal, accounting, financial and other costs associated with being a public company that is not an EGC, including mandatory adoption of new accounting pronouncements. We may also incur costs associated with compliance with the requirements of additional disclosure requirements, including Section 404(b) of the Sarbanes-Oxley Act in the event that we determine that we have become an accelerated filer or large accelerated filer.

Further, investors may find our securities less attractive because of our reliance on the foregoing exemption from Section 404(b) of the Sarbanes-Oxley Act, as well as any other exemptions available to us under U.S. federal securities laws. This could contribute to a less active trading market for our securities and prices of the securities may be more volatile or decline.

Item 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Aptorum was incorporated under the laws of the Cayman Islands on September 13, 2010. As of the issuance date of this annual report, our authorized share capital is $100,000,000.00 divided into 9,999,996,000,000 Class A Ordinary Shares with a nominal or par value of $0.00001 each and 4,000,000 Class B Ordinary Shares with a nominal or par value of $0.00001 each.

The Company now focuses all of its efforts on R&D and therefore no longer performs any therapeutic services. While the Company may commence therapeutic services in the future, as of December 31, 2024 and the date hereof, it only operates in one segment.

Aptorum is not a Chinese operating company. Aptorum is a Cayman Islands holding company with operations conducted through our subsidiaries and the variable interest entity (VIE). We have determined that we have one VIE: Libra, according to the U.S. GAAP. In accordance with ASC 810, we concluded that we are not the primary beneficiary of Libra and therefore we do not consolidate its financial statements into ours. Previously, we determined that we were the primary beneficiary of another VIE, Mios Pharmaceuticals Limited; however, Mios was dissolved in 31 October 2024 and therefore we no longer maintain any ownership over such entity. Our corporate structure is based on the equity ownership and control we have over our subsidiaries. Our corporate structure was not set up to be used to provide investors with exposure to foreign investment in China-based companies where Chinese law prohibits direct foreign investment in the operating companies. Foreign investment can be made directly into the VIE, however, your investments into Aptorum are made into the Cayman Islands holding company, not our VIE, and you may never own any equity into the VIE or any other subsidiary.

On September 25, 2020, Aptorum, via its subsidiaries, enters into a series of transactions with Accelerate Technologies Pte. Ltd.'s ("Accelerate Technologies"), the commercialization arm of the Singapore Agency for Science, Technology and Research ("A*STAR"), in relation to the research and development of Paths^{Dx} Test, a novel molecular-based rapid pathogen identification and detection diagnostics technology, through its subsidiaries. Specifically, Paths Diagnostics Pte. Limited (formerly known as Aptorum Innovations Holding Pte. Limited), one of the Company's subsidiaries, entered into an Exclusive Licence Agreement with Accelerate Technologies to co-develop the Paths^{Dx} Test technology. The term of the Exclusive Licence Agreement is described in Exhibit 4.62 on Form 20-F filed with the SEC on April 19, 2021. Furthermore, Accelerate Technologies, the inventors of the Paths^{Dx} Test technologies in A*STAR ("Founding Scientists"), Paths Diagnostics Pte. Limited, and Paths Innovations Limited (formerly known as Aptorum Innovations Holding Limited), a wholly owned subsidiary of the Company, entered into a Share Subscription & Shareholders Agreement on the same day to subscribe ordinary shares of Paths Diagnostics Pte. Limited. The shares are subscribed and issued in two tranches, the first tranche has taken place at closing of the Share Subscription & Shareholders Agreement, while the second tranche will take place after the certain first milestone is met. The total number of shares subscribed by the shareholders under the Share Subscription & Shareholders Agreement is around 2.7 million. After the two tranches of subscription, Aptorum, Accelerate Technologies and the Founding Scientists are expected to control 71.23%, 14.25% and 9.53% of the share of Paths Diagnostics Pte. Limited respectively, with 4.99% of the shares reserved for its employee share plan.

APTUS CAPITAL LIMITED, which has since been renamed to AENEAS CAPITAL LIMITED, was always under the direct ownership of Jurchen and not under the ownership chain of Aptorum Group. However, Aptus Asia Financial Holdings Limited ("AAFH"), which has since been renamed to Aeneas Group Limited, was transferred out of the Aptorum Group on November 10, 2017, to be held directly by Jurchen Investment Corporation and that subsequently, APTUS CAPITAL LIMITED was then transferred to be under AAFH.

On May 4, 2017, Mr. Huen transferred all of the ordinary shares in the Company he owned (in the amount of 2,230,760) to Jurchen, a company incorporated in the British Virgin Islands and wholly owned by Mr. Huen. On October 13, 2017, as part of the Conversions (as defined below) the ordinary shares held by Jurchen were redesignated as 223,076 Class A Ordinary Shares and 2,007,684 Class B Ordinary Shares.

On February 21 and March 1, 2017, the Company's board of directors and shareholders resolved to restructure the Company from an investment fund with management shares and non-voting participating redeemable preference shares to a holding company with operating subsidiaries, respectively (the "Restructuring Plan").

According to the Restructuring Plan, the 256,571.12 then issued participating shares with par value of $0.01 ("Participating Shares") were redeemed and 4,743,418.88 unissued Participating Shares were cancelled; following such redemption and cancellation, we no longer have any Participating Shares authorized or issued. Additionally, the Company authorized a class of securities consisting of 10,000,000 ordinary shares, par value $10.00 per share and issued 2,565,711 ordinary shares to our original investors.

During the period March 1, 2017, through October 13, 2017, an aggregate of 220,703 ordinary shares were issued at a price of approximately $39 per share in a private placement we described as a "Series A" offering. Each investor of the Series A offering, in addition to a subscription agreement, signed a shareholder agreement, which set forth the basic governance terms of the Company, as well as our capital structure. The shareholders agreement was terminated in October 2017.

On October 13, 2017, ordinary resolutions were passed at an extraordinary general meeting of the Company approving (the "Conversions"): (i) converting 7,213,587 of authorized but unissued ordinary shares into 5,457,362 authorized but unissued Class A Ordinary Shares, par value of $10.00 per share and 1,756,225 authorized but unissued Class B Ordinary Shares, par value of $10.00 per share, respectively; (ii) converting 2,493,085 ordinary shares held by three shareholders into an aggregate of 249,309 Class A Ordinary Shares and 2,243,776 Class B Ordinary Shares; and (iii) converting 293,330 ordinary shares held by 24 shareholders into an aggregate 293,330 Class A Ordinary Shares. Following these issuances, we had 27 shareholders of record.

On October 19, 2017, we changed our name from APTUS Holdings Limited to our current name, Aptorum Group Limited.

On March 23, 2018, Jurchen transferred 44,615 Class A Ordinary Shares and 401,537 Class B Ordinary Shares to CGY Investments Limited, a company incorporated in Hong Kong and which we deem Mr. Darren Lui jointly controls and/or of which he has substantial influence on the disposition rights and voting rights of such shares. Following this transfer, Jurchen owns approximately 33% and 72% of our Class A Ordinary Shares and Class B Ordinary Shares, respectively.

On December 17, 2018, the Company consummated its IPO of 76,142 Class A Ordinary Shares. The Registration Statement was declared effective by the U.S. Securities and Exchange Commission on December 3, 2018 (the "Effective Date"). The shares were sold at a price of $158 per share, generating gross proceeds to the Company of approximately $12,030,420.

On May 26, 2021, the Company entered into a private placement shares purchase agreement with Jurchen, issuing 138,793 Class A Ordinary Shares, par value $10 per share, at $28.82 per share, representing a 10% premium to the last closing price of the Company's Class A Ordinary Shares on the NASDAQ stock exchange on that date. The Company received aggregate gross proceeds of $4,000,000 from the purchase of these shares. Following the purchase, Mr. Huen's total shareholding represented 55.52% of the total issued share capital of the Company.

On January 23, 2023, the Company effectuated a ten-for-one share consolidation of its authorized share capital, such that every 10 Class A Ordinary Shares, par value of US$1.00 per share, in the authorized share capital of the Company (including issued and unissued share capital) were consolidated into 1 Class A Ordinary Share, par value of US$10.00 per share, and that every 10 Class B Ordinary Shares, par value of US$1.00 per share in the authorized share capital of the Company (including issued and unissued share capital) were consolidated into 1 Class B Ordinary Share, par value of US$10.00 per share (the "Share Consolidation" or "Reverse Split").

On February 21, 2023, the shareholders of the Company approved a merger of the Company with Aptorum Group Cayman Limited, a wholly owned subsidiary of the Company, whereby the Company was the surviving company, on the terms of the plan of merger that includes the change in par value in the authorized shares of the Company from $10 to $0.00001. In addition, among other things, the shareholders approved to increase the voting rights of the Class B Ordinary Shares from 10 votes per share to 100 votes per share, and to increase the number of Class A Ordinary Shares authorized to 9,999,996,000,000 shares, par value $0.00001 each. These corporate actions were effective as of February 21, 2023.

In June 2023, we entered into securities purchase agreements to sell $3,000,000 unsecured convertible notes to 4 investors (the "June 23 Notes"). All the June 23 Notes were subsequently converted into an aggregate of 1,000,000 Class A Ordinary Shares, par value $0.00001 per share.

In September 2023, we entered into a securities purchase agreement to sell a $3,000,000 unsecured convertible note ("Sep 23 Note") to Jurchen Investment Corporation, our largest shareholder. The Sep 23 Note is convertible into our Class A Ordinary Shares and have a maturity date that is 24 months from the issuance date, although upon such date the investor has the right to extend the term of the Note for twelve (12) months or more or such term subject to mutual consent. The Sep 23 Note has an interest rate of 6% per annum and a conversion price of $2.42 per share. The Sep 23 Note is secured by a first priority lien and security interest on certain shares that we own ("Collateral"). Upon our disposal of all or a portion of the Collateral, the investor has the right, to request that we prepay the then-remaining outstanding balance of the Sep 23 Note, in part or in full and we can make that payment in cash or in shares.

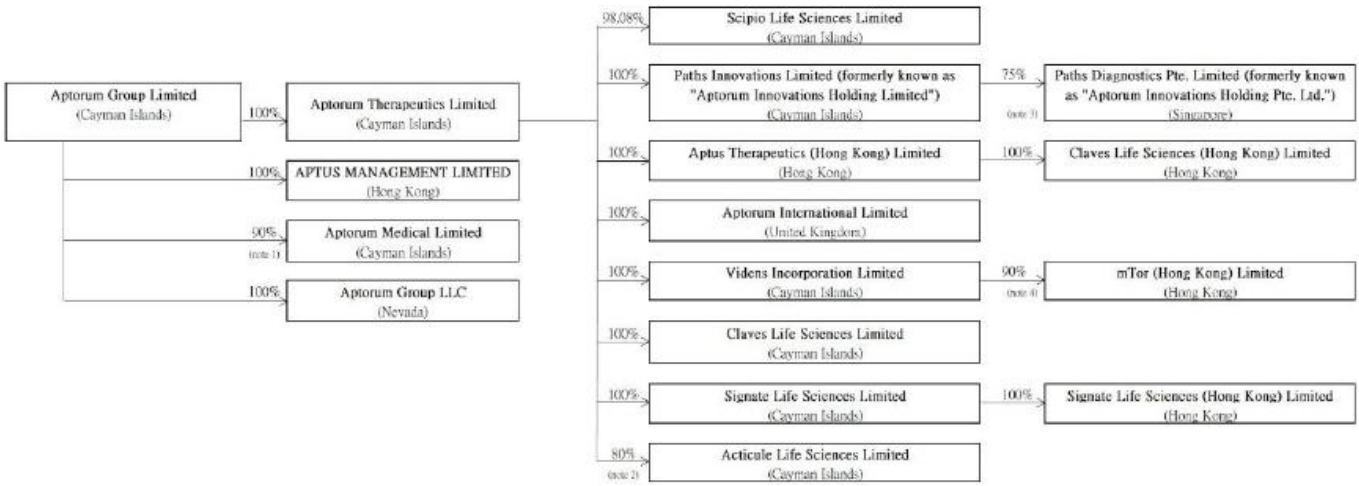
On March 1, 2024, we entered into an Agreement and Plan of Merger with YOOV Group Holding Limited, a company organized under the laws of British Virgin Islands ("YOOV"), pursuant to which YOOV was to become one of our wholly owned subsidiaries. However, on October 25, 2024, the parties to the Agreement and Plan of Merger entered into a termination agreement (the "Termination Agreement"), pursuant to which the parties agreed to terminate the Agreement and Plan of Merger on the date thereof (the "Termination Date"), and such agreement became null and void and of no further force or effect.

On April 8, 2024, CGY Investments Limited and DSF Investment Holdings Limited voluntarily converted 401,537 Class B Ordinary Shares and 45,305 Class B Ordinary Shares, respectively into Class A Ordinary Shares on a one-for-one basis. Upon conversion, 1,796,934 Class B Ordinary Shares were issued and outstanding, CGY Investments Limited owned 533,575 Class A Ordinary Shares and did not own any Class B Ordinary Share; and DSF Investment Holdings Limited owned 45,305 Class A Ordinary Shares and did not own any Class B Ordinary Share.

On January 2, 2025, the Company entered into a certain securities purchase agreement with certain non-affiliated institutional investors pursuant to which the Company sold 1,535,000 Class A ordinary shares of the Company, par value $0.00001 per share at a per share price of $2.00 in a registered direct offering, for gross proceeds of $3,070,000.

Over the past three years, we have invested approximately $0.2 million towards our principal capital expenditures, which include laboratory equipment, leasehold improvements, and other equipment.

The following diagram illustrates our corporate structure as of the date of this annual report:



Note 1: Dr. Clark Cheng, a former Executive Director of Aptorum Group, holds the remaining 10% shareholding of Aptorum Medical Limited.

Note 2: Angen Funds Limited, a company designated by an investor of ALS series projects, holds the remaining 20% shareholding of Acticule Life Sciences Limited.

Note 3: Accelerate Technologies Pte. Ltd., the commercialization arm of the Singapore Agency for Science, Technology and Research ("A*STAR"), hold 15% shareholding of Paths Diagnostics Pte. Limited. The inventors of Paths^{Dx} Test technologies in A*STAR hold the remaining 10% of shareholding of Paths Diagnostics Pte. Limited.

Note 4: An investor of project VLS-2 holds the remaining 10% shareholding of mTor (Hong Kong) Limited.

Currently, we conduct the majority of our operations through the following subsidiaries: Aptorum Therapeutics Limited, Acticule Life Sciences Limited and Paths Diagnostics Pte. Limited. All investments into our company are into the parent company, Aptorum Group Limited, a Cayman Islands exempted company with limited liability whose principal place of business is in Hong Kong; you may never hold direct equity interests in our subsidiaries or the VIEs.

In accordance with the provisions of Accounting Standards Codification ("ASC") 810, Consolidation, we consolidate any VIE of which we are regarded as the primary beneficiary for accounting purposes. The typical condition for a controlling financial interest ownership is holding a majority of the voting interests of an entity; however, a controlling financial interest may also exist in entities, such as VIEs, through arrangements that do not involve controlling voting interests. We have determined that we have one VIE, namely, Libra, according to the U.S. GAAP. In accordance with ASC 810, we have considered Libra's memorandum and article of association, and determined that we do not have such power over Libra's research and development activities, which activities most significantly impact Libra's economic performance. Accordingly, we determined that we are not regarded as the primary beneficiary of Libra for accounting purposes. Libra did not have any operations during the year ended December 31, 2024.

Foreign Private Issuer Status

We are a foreign private issuer within the meaning of the rules under the Exchange. As such, we are exempt from certain provisions applicable to United States domestic public companies. For example:

- we are not required to provide as many Exchange Act reports, or as frequently, as a domestic public company;
- for interim reporting, we are permitted to comply solely with our home country requirements, which are less rigorous than the rules that apply to domestic public companies;
- we are not required to provide the same level of disclosure on certain issues, such as executive compensation;
- we are exempt from provisions of Regulation FD aimed at preventing issuers from making selective disclosures of material information;
- we are not required to comply with the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; and
- we are not required to comply with Section 16 of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and establishing insider liability for profits realized from any "short-swing" trading transaction.

B. Business Overview

Overview of our Company

Aptorum is not a Chinese operating company. Aptorum is a Cayman Islands holding company with operations conducted through our subsidiaries and the variable interest entity (VIE). We have determined that we have one VIE: Libra, according to the U.S. GAAP. In accordance with ASC 810, we concluded that we are not the primary beneficiary of Libra and therefore we do not consolidate its financial statements into ours. Previously, we determined that we were the primary beneficiary of another VIE, Mios Pharmaceuticals Limited; however, Mios was dissolved in 31 October 2024 and therefore we no longer maintain any ownership over such entity. Our corporate structure is based on the equity ownership and control we have over our subsidiaries. Our corporate structure was not set up to be used to provide investors with exposure to foreign investment in China-based companies where Chinese law prohibits direct foreign investment in the operating companies. Foreign investment can be made directly into the VIE, however, your investments into Aptorum are made into the Cayman Islands holding company, not our VIE, and you may never own any equity into the VIE or any other subsidiary.

Our current corporate structure does not contain any variable interest entity in mainland China and we do not have intention establishing any VIEs in mainland China in the future. However, if in the future there is any significant change to the current political arrangements between mainland China and Hong Kong and mainland China's expanded authority in Hong Kong result in the PRC regulatory authorities disallowing our current corporate structure, or if in the future our structure were to contain a VIE and the mainland PRC regulatory authorities expand to Hong Kong and disallow our corporate structure, it would likely result in a material adverse change in the VIE's operations, and the value of our securities may decline significantly in value or become worthless.

Although currently we do not have any business operations or VIE in mainland China and we believe that the laws and regulations of the PRC applicable in China do not currently have any material impact on our business, financial condition or results of operations, we face risks and uncertainties associated with the complex and evolving PRC laws and regulations and as to whether and how the recent PRC government statements and regulatory developments, such as those relating to our VIE or subsidiaries, data and cyberspace security, and anti-monopoly concerns, would be applicable to Scipio, given its substantial operations in Hong Kong and the Chinese government's significant oversight authority over the conduct of business in Hong Kong.

In light of China's recent expansion of authority in Hong Kong, we are subject to the risks of uncertainty about any future actions of the PRC government or authorities in Hong Kong. The Chinese government may intervene or influence our current and future operations in Hong Kong at any time, or may exert more control over offerings conducted overseas and/or foreign investment in issuers likes ourselves. We believe that, on the basis that we currently do not have any business operations in mainland China, we currently are not required to obtain approvals from Chinese authorities to operate our business or list on the U.S. exchanges and offer securities; specifically, neither our VIE nor any of the subsidiaries is currently required to obtain any permission or approval from the China Securities Regulatory Commission ("CSRC"), Cyberspace Administration of China ("CAC") or any other PRC governmental authority to operate its business or for us to continue to list our securities on a U.S. securities exchange or issue securities to foreign investors. However, there is no assurance that there will not be any changes in the economic, political and legal environment in Hong Kong in the future. Should the PRC government choose to affect operations of any company with any level of operations in Hong Kong, or should certain PRC laws and regulations or these statements or regulatory actions become applicable to our VIE or subsidiaries in the future. Such governmental actions: (i) could significantly limit or completely hinder our ability to continue our operations; (ii) could significantly limit or hinder our ability to offer or continue to offer our Class A Ordinary Shares to investors; and (iii) may cause the value of our Class A Ordinary Shares to significantly decline or be worthless.

We are also aware that recently, the PRC government initiated a series of regulatory actions and statements to regulate business operations in certain areas in mainland China with little advance notice, including cracking down on illegal activities in the securities market, enhancing supervision over mainland Chinese companies listed overseas using variable interest entity structure, adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement. Nevertheless, since these statements and regulatory actions are new, it is highly uncertain how soon the legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any. It is also highly uncertain what the potential impact such modified or new laws and regulations will have on the VIEs' daily business operation, and the continued listing of our Class A Ordinary Shares on a U.S. or other foreign exchanges. If any or all of the foregoing were to occur, it may significantly limit or completely hinder our ability to complete this offering or cause the value of our Class A Ordinary Shares to significantly decline or become worthless. See "Risk Factors - Risks Related to Our Corporate Structure" and "Risk Factors - Risks Relating to Doing Business in Hong Kong".

In addition, our Class A Ordinary Shares may be prohibited from trading on a national exchange or over-the-counter under the Holding Foreign Companies Accountable Act, as amended (the "HFCA Act") if the Public Company Accounting Oversight Board (United States) (the "PCAOB") is unable to inspect our auditors for two consecutive years beginning in 2021. Our auditor, Marcum Asia CPAs LLP, have been inspected by the PCAOB on a regular basis, and Marcum Asia CPAs LLP is not subject to the determinations announced by the PCAOB on December 16, 2021. If trading in our Class A Ordinary Shares is prohibited under the HFCA Act in the future because the PCAOB determines that it cannot inspect or fully investigate our auditor at such future time, Nasdaq may determine to delist our Class A Ordinary Shares and trading in our Class A Ordinary Shares could be prohibited. While our auditor is based in the U.S. and is registered with the PCAOB and subject to PCAOB inspection, in the event it is later determined that the PCAOB is unable to inspect or investigate completely our auditor because of a position taken by an authority in a foreign jurisdiction, then such lack of inspection could cause trading in our Ordinary Shares to be prohibited under the HFCA Act, and ultimately result in a determination by a securities exchange to delist our Ordinary Shares. On August 26, 2022, the PCAOB signed a Statement of Protocol (the "SOP") Agreement with the CSRC and China's Ministry of Finance. The SOP Agreement, together with two protocol agreements (collectively, "SOP Agreements"), governing inspections and investigations of audit firms based in mainland China and Hong Kong, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. Pursuant to the fact sheet with respect to the Protocol disclosed by the SEC, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation and has the unfettered ability to transfer information to the SEC. On December 15, 2022, the PCAOB Board determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and voted to vacate its previous determinations to the contrary. However, should PRC authorities obstruct or otherwise fail to facilitate the PCAOB's access in the future, the PCAOB Board will consider the need to issue a new determination.

The Company now focuses all of its efforts on R&D and therefore no longer performs any therapeutic services. While the Company may commence therapeutic services in the future, as of December 31, 2024 and the date hereof, it only operates in one segment.

Cash Transfers and Dividend Distribution

Our management is directly supervising cash management. Our finance department is responsible for establishing the cash management policies and procedures among our departments and the operating entities. Majority of the cash are managed by a few of the subsidiaries of Aptorum Group. Each department or operating entity initiates a cash request by putting forward a payment requisition form, which explains the specific amount and timing of cash requested, and submitting it to designated management members of our Company, based on the amount and the nature of payment. The designated management member examines and approves the cash transfer based on the sources of cash and the priorities of the needs, and submit it to the cashier specialists of our finance department for a second review. Other than the above, we currently do not have other cash management policies or procedures that dictate how funds are transferred.

We are permitted under the laws of Cayman Islands to provide funding to our subsidiaries through loans or capital contributions without restrictions on the amount of the funds.

As of the date of this annual report, neither our VIE nor any of our subsidiaries have made any dividends or distributions to our Company and our Company has not made any dividends or distributions to our shareholders. We intend to keep any future earnings to finance the expansion of our business, and we do not anticipate that any cash dividends will be paid in the foreseeable future. Subject to the passive foreign investment company ("PFIC") rules, the gross amount of distributions we make to investors with respect to our Class A Ordinary Shares (including the amount of any taxes withheld therefrom) will be taxable as a dividend, to the extent that the distribution is paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles.

Business Overview

We are a clinical stage biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutic assets to treat diseases with unmet medical needs, particularly in oncology (including orphan oncology indications) and infectious diseases. The pipeline of Aptorum is also enriched through the co-development of Paths^{Dx} Test, a novel molecular-based rapid pathogen identification and detection diagnostics technology, with Accelerate Technologies Pte Ltd, commercialization arm of the Singapore's Agency for Science, Technology and Research.

The Company now focuses all of its efforts on R&D and therefore no longer performs any therapeutic services. While the Company may commence therapeutic services in the future, as of December 31, 2024 and the date hereof, it only operates in one segment.

Our goal is to develop a broad range of novel and repurposed therapeutics and diagnostics technology across a wide range of disease/therapeutic areas. Key components of our strategy for achieving this goal include: (for details of our strategy, See "Business Overview – Our Strategy")

- Developing therapeutic and diagnostic innovations across a wide range of disease/therapeutic areas;
- Selectively expanding our portfolio with potential products that may be able to attain orphan drug designation and/or satisfy current unmet medical needs;
- Collaborating with leading academic institutions and CROs;
- Expanding our in-house pharmaceutical development center;
- Leveraging our management's expertise, experience and commercial networks;
- Obtaining and leveraging government grants to fund project development.

We have devoted a substantial portion of the proceeds from our offerings, to our Lead Projects. Our Lead Projects are ALS-4, SACT-1 and Paths^{Dx} Test. In March 2023, we announced that we completed the Pre-IND discussions with the US FDA on ALS-4. With the positive feedback on the overall development strategy from the US FDA, we are proceeding towards the IND submission of ALS-4. In March 2023, we also announced the completion of the End of Phase 1 (EOP1) meeting of SACT-1 with the US FDA. The FDA generally agreed with the chemistry-manufacturing-control (CMC) strategy and our proposed clinical development plan for SACT-1 Phase 1/2 trials. We commenced clinical validation of our molecular based Paths^{Dx} Test and will continue to undergo validations in parallel with its pre-commercialization process.

During the second quarter of 2023, the Company made a decision to streamline its operations by terminating clinic services and suspending non-lead R&D projects. This measure is aimed at optimizing the allocation of our resources and focusing our efforts on advancing our lead projects, which hold the most promise for commercial success and beneficial impact. This decision aligns with our commitment to enhance shareholder value and effectively drive our core objectives forward in the competitive landscape.

Prior to March 2017, the Company had pursued passive healthcare related investments in early-stage companies primarily in the United States. However, we have since ceased pursuing further passive investment operations and intend to exit all such portfolio investments over an appropriate timeframe to focus resources on our current business.

On September 25, 2020, Aptorum, via its subsidiaries, enters into a series of transactions with Accelerate Technologies Pte. Ltd.'s ("Accelerate Technologies"), the commercialization arm of the Singapore Agency for Science, Technology and Research ("A*STAR"), in relation to the research and development of Paths^{Dx} Test, a novel molecular-based rapid pathogen identification and detection diagnostics technology, through its subsidiaries. Specifically, Paths Diagnostics Pte. Limited, one of the Company's subsidiaries, entered into an Exclusive Licence Agreement with Accelerate Technologies to co-develop the Paths^{Dx} Test technology. The term of the Exclusive Licence Agreement is described in Exhibit 4.62 on Form 20-F filed with the SEC on April 19, 2021. Furthermore, Accelerate Technologies, the inventors of the Paths^{Dx} Test technologies in A*STAR ("Founding Scientists"), Paths Diagnostics Pte. Limited, and Paths Innovations Limited, a wholly owned subsidiary of the Company, entered into a Share Subscription & Shareholders Agreement on the same day to subscribe ordinary shares of Paths Diagnostics Pte. Limited. The shares are subscribed and issued in two tranches, the first tranche has taken place at closing of the Share Subscription & Shareholders Agreement, while the second tranche will take place after the certain first milestone is met. The total number of shares subscribed by the shareholders under the Share Subscription & Shareholders Agreement is around 2.7 million. After the two tranches of subscription, Aptorum, Accelerate Technologies and the Founding Scientists are expected to control 71.23%, 14.25% and 9.53% of the share of Paths Diagnostics Pte. Limited respectively, with 4.99% of the shares reserved for its employee share plan.

On December 30, 2020, Paths Innovations Limited, one of the Company's wholly owned subsidiaries, entered into an Evaluation Agreement with Illumina Inc ("Illumina"). Pursuant to the agreement, Paths Innovations Limited will evaluate the data and performance of Illumina's sequencing technology based on the workflow of Paths^{Dx} Test, a novel molecular-based rapid pathogen identification and detection diagnostics technology, at Paths Innovations Limited's Singapore based evaluation site.

In May 2023, our subsidiary, Aptorum Therapeutics Limited ("ATL"), a company incorporated under the laws of Grand Cayman Islands entered into a non-binding Letter of Intent and Term Sheet ("Term Sheet") to merge ("Transaction") its 100% subsidiary, Paths Innovation Limited and its underlying business (collectively "PathsDx Group") with Universal Sequencing Technology Corporation ("UST"), a San Diego and Boston based US company dedicated to the development and commercialization of advanced proprietary DNA sequencing technologies. Paths Innovation Limited currently holds, through its majority owned subsidiary Paths Diagnostics Pte. Limited, the PathsDx technology – a liquid biopsy NGS based technology for the diagnostics of infectious diseases. As consideration of the transaction upon closing, ATL will become a shareholder of the combined company. The transaction and other ancillary distributions, where relevant, remain subject to, among other matters, the execution of a mutually agreeable definitive agreement, completion of due diligence and subject to several conditions including, but not limited to, director and shareholder approvals.

Our Strategy

The Company will position itself to catalyze the development and improvement of a broad range of novel and repurposed therapeutics and diagnostics across a wide range of disease/therapeutic areas. Failure to achieve positive results in at least one of the programs for a Lead Project could have a material adverse effect on the Company's prospects and business.

To achieve this goal, we are implementing the following strategies:

- **Selectively expanding our portfolio with potential products that may be able to attain orphan drug designation and/or satisfy current unmet medical needs.** We have selected innovations for development which we believe are of superior scientific quality, whilst taking into account the potential market size and demand for same, for example, taking into consideration whether the relevant product can satisfy significant unmet medical needs. In particular, Aptorum Group Limited has established a Scientific Advisory Board, which helped us to select our current projects and which we expect will provide input from a scientific perspective towards any future opportunities for acquiring or licensing life science innovations. We intend to continue expanding our line of projects under development, and subject to our financial and other resource limitations, exploring acquisitions or licenses of additional products which may be able to attain orphan drug designations (e.g., rare types of cancer) or satisfy significant unmet medical needs and that show strong preclinical and/or early clinical data to provide promising opportunities for clinical and commercial success.

- **Collaborating with leading academic institutions and CROs.** In building and developing our product portfolio, we believe that accessing external innovation, expertise and technology through collaboration with leading academic institutions and CROs is a vital and cost-efficient strategy. We have established strong relationships with leading academic institutions around the world and expect to continue to strengthen our collaborations by, for example, seeking to provide their affiliated Principal Investigators resources through sponsorship to conduct further research in specialty fields of interest and association with personnel connected to our current project companies, in exchange for obtaining for the Company the first right to negotiate for an exclusive license to any resulting innovations. In addition, we have entered and will continue to actively source arrangements with pharmaceutical companies, in most cases in roles as contract research organizations, to streamline the development of our projects. This may include outsourcing part of the preclinical, clinical studies and clinical supplies manufacturing to externally accredited cGLP, cGMP and cGCP standard contract research organizations or laboratories in order to attain the required studies for submission to the regulatory authorities as part of the clinical development plan. (See "Item 4. Information on the Company – B. Business Overview – Arrangements with Other Parties")

- **Obtaining and leveraging government grants to fund project development.** Governments across the world pays close attention to the development of the biotechnology sector and provides support and funding. We intend to aggressively seek government support from the governments in the United States, the United Kingdom, Hong Kong, Singapore and elsewhere for our product development and to facilitate the development of some of our projects.

Arrangements with Other Parties

As mentioned above, part of our business model includes collaborating with research entities such as academic institutions and CROs, as well as highly regarded experts in their respective fields. We engage these entities and researchers either for purposes of exploring new innovations or advancing preclinical studies of our existing licensed drug candidates. Although the financial cost of these arrangements does not represent a material expense to the Company, the relationships we can access through, specifically, sponsored research arrangements ("SRAs") with academic institutions and organizations can provide significant value for our business; for example, we may decide whether to continue development of certain early-staged projects and/or out-license a project based on the data and results from research governed by SRAs. However, as of the date of this annual report, we do not consider the particulars of any of our SRAs to be material to the success of our current business plans.

Our drug discovery programs are based upon licenses from universities and are mainly conducted in universities via SRAs. As for the development of our drug candidates, our R&D Center conducts part of the CMC work. However, since our current facilities are not cGMP, cGLP or cGCP qualified, we will have to rely on CROs to conduct that type of work, if and when our drug candidates reach the level of development that requires such qualification.

Lead Projects

We are operating and managing the development of our drug candidates through various subsidiaries. Each candidate is being researched in a subsidiary with a medical/scientific area of focus related to the drug candidate in development. We refer to these as our "Project Companies" and their products or areas of focus as our Lead Projects (i.e., ALS-4, SACT-1 and Paths^{Dx} Test). The selection of a drug candidate is based on our estimate of the market potential for that candidate, the scientific expertise required to develop it, and our overall corporate strategy, including our ability to commit personnel and future investment to that candidate.

To pursue a number of our current projects, our Project Companies have entered into standard license agreements with various universities and licensing entities customized to the nature of each project. These license agreements largely contain the same terms, as is typically seen in license agreements for an early-stage life science invention; such terms include a worldwide license with licensed field comprising indications in the intended treatment areas, having upfront payments, certain royalty rates, sublicensing royalties, as well as provisions for payments upon occurrence of development and/or regulatory milestones. Under the license agreements, the Project Company must also adhere to certain diligence obligations (which may include specific diligence) and the types of activities or achievements that will satisfy those diligence obligations. Additionally, our Project Company may or may not be required to obtain prior consent from the licensor to sublicense the invention. The license terms of our Lead Projects are discussed in detail below.

Generally speaking, pharmaceutical development consists of preclinical and clinical phases. The preclinical phase can further sub-divided into the following stages:

- Target Identification & Selection: The target is the naturally existing cellular or modular structure that appears to have an important role in a particular disease pathway and will be targeted by the drug that will subsequently be developed. Target validation techniques for different disease areas can be very different but typically include from in vitro and in silico methods through to the use of whole animal models.

- Lead Discovery: Following "Target Identification & Selection," compound screening assays are developed as part of the Lead Discovery. 'Lead' molecules can mean slightly different things to different researches or companies, but in this annual report, we refer to Lead Discovery as the process of identifying one or more small molecules with the desired activity against the identified targets. Leads can be identified through one or more approaches, which can depend on the target and what, if any, previous knowledge exists.

- Lead Optimization: In this stage of the drug discovery process, the aim is to produce a preclinical drug candidate by maintaining the desired and favorable properties in the lead compounds, while repairing or reducing deficiencies in their structures. For example, to optimize the chemical structures to improve, among others, efficacy, reduce toxicity, improve metabolism, absorption and pharmacokinetic properties.

- CTA-Enabling Studies: Includes all the essential studies such as GLP toxicology studies, pharmacology and efficacy, pharmacokinetics, in vitro metabolism, CMC studies, and the data of which are used for CTA submission.

- IND-Enabling Studies: Includes all the essential studies such as GLP toxicology studies, pharmacology and efficacy, pharmacokinetics, in vitro metabolism, CMC studies, and the data of which are used for IND submission.

- In vitro validation: At this stage, the efficacy and safety of a drug candidate are assessed at cellular levels.

- In vivo validation: At this stage, the efficacy, safety and pharmacokinetic of a drug candidate are assessed in animal models.

- IND Preparation and Submission: Preparation of a package of documents for different sections such as CMC, clinical, nonclinical, etc. and getting them reviewed, approved and final checked and followed by submission to regulatory agencies.

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

- **Phase 1.** Phase 1 includes the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in Phase 1 studies varies with the drug, but is generally in the range of twenty to eighty.

- **Phase 2.** Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people.

- **Phase 3.** Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies are designed to provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

Our non-therapeutics projects can be sub-divided into the following stages:

- Development and Experimentation: Early development work for proof-of-concept.

- Product Optimization: The practice of making changes or adjustments to a product to make it more desirable.

- Clinical Validation: Confirming the performance of a technology using clinical/patient samples.

- Pre-commercialization preparation: The logistics that need to be accomplished before commercialization.

- Formulation: Preparation of a marketed dosage form from active ingredients and excipients/additives.

- Commercialization: The process of introducing a new product or production method into commerce—making it available on the market.

→ Lead Projects

Projects	Candidate / Modality	Indication	Development Stage						
			Target Identification & Selection	Lead Discovery	Lead Optimization	IND (or IND equivalent) Enabling	Clinical Trial Application Submission	Phase I	Phase II/III
Acticule's Series									
ALS-4	Small molecule	Treatment of bacterial infections caused by Staphylococcus aureus including MRSA							

Projects	Candidate / Modality	Indication	Computational Discovery	In Vitro Validation	Existing Ph I/II Clinical Safety Data	In Vivo Validation	IND Preparation & Submission	Phase I	Phase Ib/IIa
SACT's Series									
SACT-1	Repurposed small molecule	Neuroblastoma and other potential cancer types							

Project	Candidate / Modality	Indication	Development and Experimentation	Product Optimization	Clinical Validation and Pre Commercialization Preparation	Commercialization
RPIDD	Liquid biopsy rapid pathogen diagnostics	Pathogen molecular diagnostics				

ALS-4: Small molecule for the treatment of bacterial infections caused by Staphylococcus aureus including but not limited to Methicillin-resistant Staphylococcus aureus ("MRSA")

Just as certain strains of viruses, such as human immunodeficiency virus ("HIV") and influenza have developed resistance to drugs developed to treat them, certain bacteria such as *Staphylococcus aureus*, *Mycobacterium tuberculosis* and *Pseudomonas aeruginosa* have become "superbugs", having developed resistance to many, if not all, of the existing drugs available to treat them, rendering those treatments ineffective in many instances. MRSA is one such bacterium, a gram-positive bacterium that is genetically different from other strains of Staphylococcus aureus. Staphylococcus aureus and MRSA can cause a variety of problems ranging from skin infections and sepsis to pneumonia and bloodstream infections. It is estimated that about one out of every three people (33%) carry Staphylococcus aureus in their nose, usually without any illness; about two in a hundred (2%) carry MRSA (source: https://www.cdc.gov/mrsa/tracking/index.html). Both adults and children may carry MRSA.

Most MRSA infections occur in people who have been in hospital or other health care settings, such as nursing homes and dialysis centers (source: https://www.mayoclinic.org/diseases-conditions/mrsa/symptoms-causes/syc-20375336), which is known as Healthcare-Associated MRSA ("HA-MRSA"). HA-MRSA infections are typically associated with invasive procedures or devices, such as surgeries, intravenous tubing or artificial joints. Another type of MRSA infection, known as Community-Associated MRSA ("CA-MRSA"), has occurred in wider community among healthy people. It often begins as a painful skin boil and spreads by skin-to-skin contact. About 85% of serious, invasive MRSA infections are healthcare associated infections (https://www.cdc.gov/media/pressrel/2007/r071016.htm). The incidence of CA-MRSA varies according to population and geographic location. In the U.S., more than 94,000 people develop serious MRSA infection and about 19,000 patients die as a result each year (https://www.cdc.gov/media/pressrel/2007/r071016.htm). According to the US Centers for Disease Control and Prevention ("CDC"), Staphylococcus aureus, including MRSA, caused about 11% of healthcare-associated infections in 2011 (source: http://www.healthcommunities.com/mrsa-infection/incidence.shtml). Each year in the U.S., around one out of every twenty-five hospitalized patients contracts at least one infection in the hospital (N Engl J Med. 2014, 27;370(13):1198-208). In the U.S., there were over 80,000 invasive MRSA infections and 11,285 related deaths in 2011 (source: https://edition.cnn.com/2013/06/28/us/mrsa-fast-facts/index.html). Indeed, severe MRSA infections most commonly occur during or soon after inpatient medical care. More than 290,000 hospitalized patients are infected with Staphylococcus aureus and of these staphylococcal infections, approximately 126,000 are related to MRSA (source: http://www.healthcommunities.com/mrsa-infection/incidence.shtml).

ALS-4 is a small drug molecule which appears to target the products produced by bacterial genes that facilitate the successful colonization and survival of the bacterium in the body or that cause damage to the body's systems. These products of bacterial genes are referred to as "virulence expression." Targeting bacterial virulence is an alternative approach to antimicrobial therapy that offers promising opportunities to overcome the emergence and increasing prevalence of antibiotic-resistant bacteria.

Professor Richard Kao from The University of Hong Kong (who is also the Founder and Principal Investigator of Acticule and Inventor of ALS-1, ALS-2, ALS-3 and ALS-4) initiated a high throughput approach for screening compounds which are active against virulence expression, which resulted in the discovery of ALS-1, ALS-2, ALS-3 and ALS-4.

ALS-4 targets an enzyme essential for Staphylococcus aureus (including MRSA) survival in vivo. This enzyme is involved in the production of Staphyloxanthin, a carotenoid pigment produced by Staphylococcus aureus including MRSA, and is responsible for the characteristic golden color. This pigment has proven to be an important factor in promoting bacterial invasion as well as rendering the bacteria resistant to attack from reactive oxygen species (ROS) and neutrophils. In other words, pigmented bacteria have increased resistance to the host's immune defenses. ALS-4 may have particular value if it can be shown to be an effective therapy in situations where a Staphylococcus aureus infection is resistant to available antibiotics (i.e., where the pathogen is MRSA).

In a study by the inventor, Prof. Richard Kao, ALS-4 demonstrates potent activity against Staphylococcus aureus pigment formation in vitro, as indicated in Figure 1, with an IC_{50} (IC_{50} is defined as the concentration of a drug which inhibits half of the maximal response of a biochemical process. In this case, inhibition of the formation of the golden pigment is the response) equal to 20 nM.

Figure 1

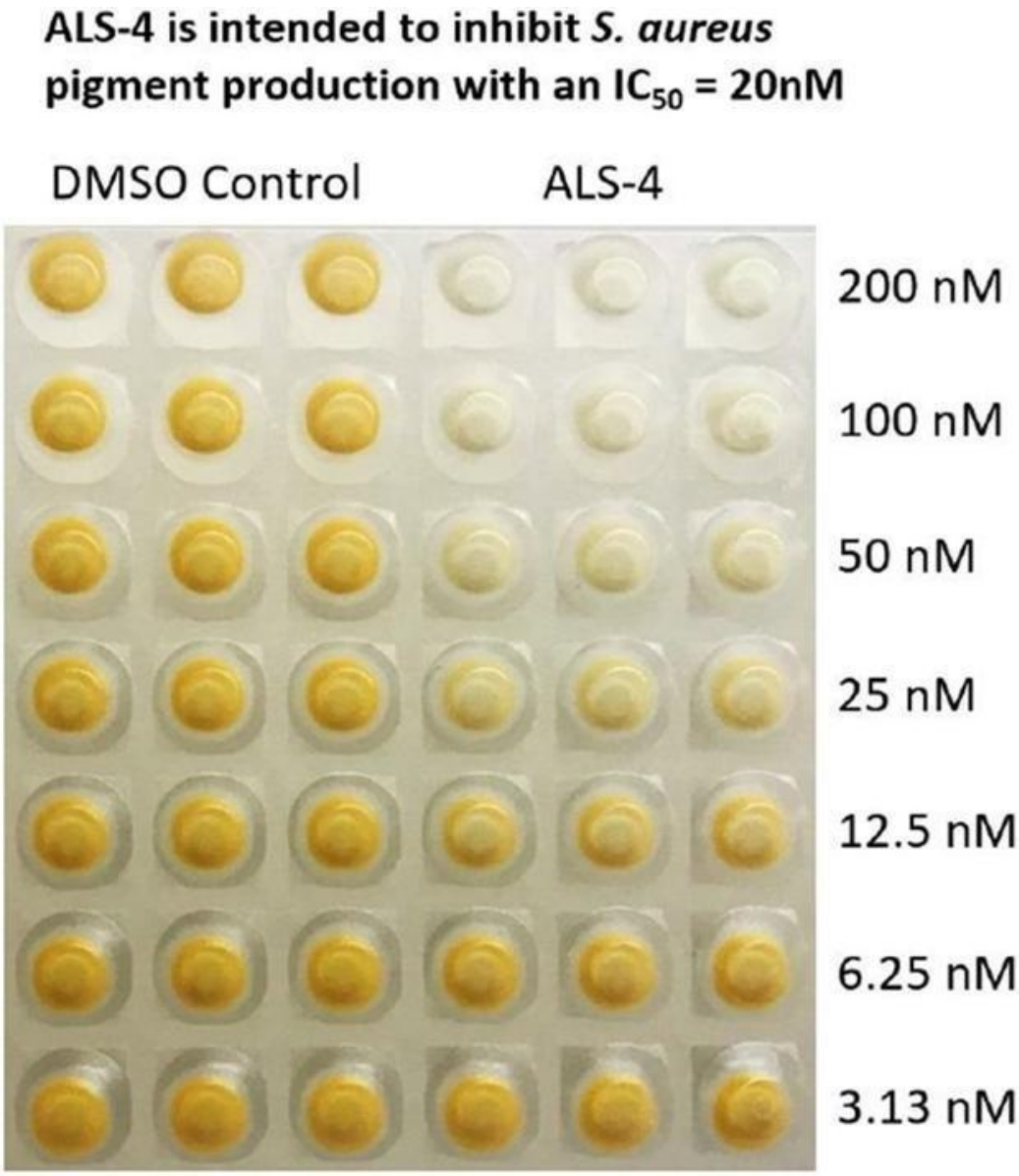
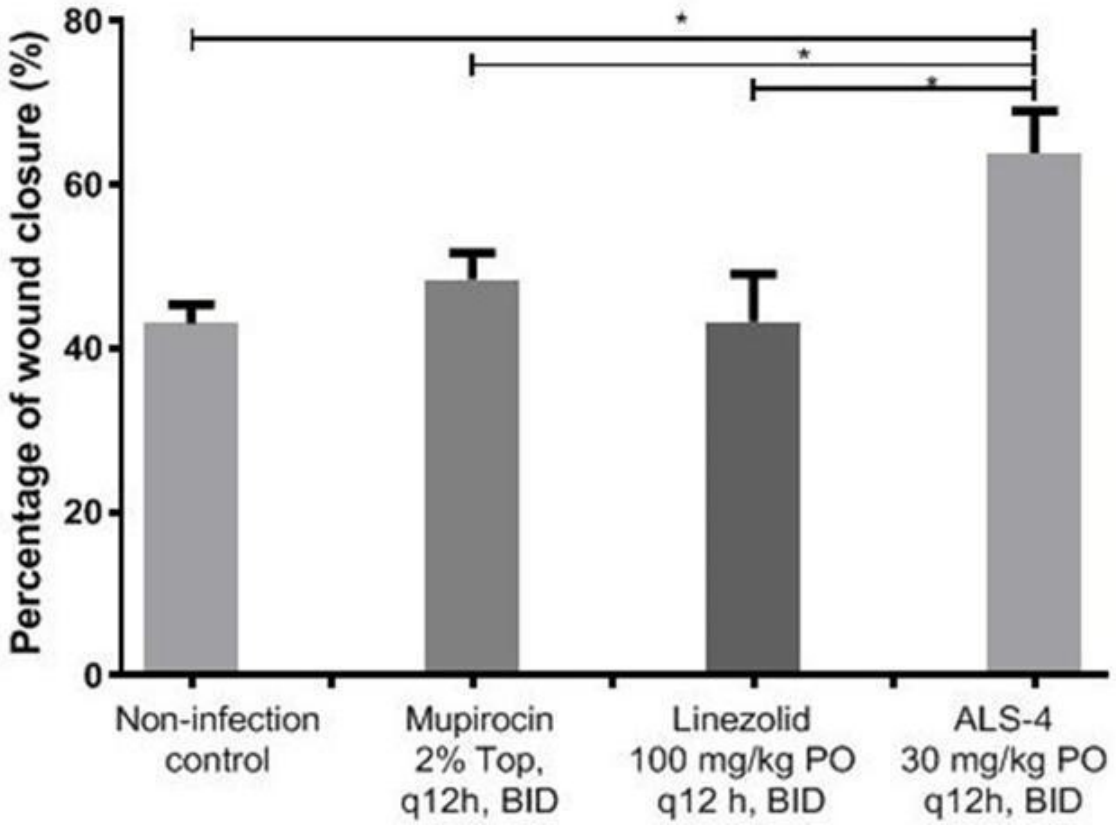


Figure 1: In vitro pigment inhibition by compound ALS-4: Inhibition of staphyloxathin (the golden pigment in *S. Aureus*) in the presence of increasing concentrations of ALS-4

Efficacy of ALS-4 in a MRSA Wound Infection Mouse Model

A study conducted by a third-party contract research organization, assessed ALS-4's effect in the healing of open wounds infected with MRSA in a mouse model. Compared with topical dosing of 2% Mupirocin and oral dosing of Linezolid at 100mg/kg twice a day, oral dosing of ALS-4 at 30mg/kg twice a day showed statistically significant improvement in wound healing. Specifically, at the end of the study on Day 7, ALS-4 exhibited 63.8% of wound closure compared with 48.4% for oral Linezolid and 43.2% for topical Mupirocin 2%. The results are further illustrated in the graph below.

Figure 2



* Unpaired student's t-test, $p<0.05$

Figure 2: Result of study on ALS-4's effect in the healing of open wounds infected with MRSA in a mouse model

Efficacy of ALS-4 in a Bacteraemia Mouse Model

In a further round of *in vivo* studies, conducted by a third-party contract research organization, in a non-lethal MRSA bacteraemia mouse model, the mice were orally administered with different doses of ALS-4 from 0.3 to 30mg/kg twice a day for 7 days, compared to those who received vancomycin only group (3mg/kg of vancomycin administered intravenously) and a no treatment control group.

At the conclusion of the study on Day 7, ALS-4 brought a statistically significant reduction in bacterial counts in major organs such as the kidneys, lungs, liver and spleen compared with the no drug control and vancomycin only groups (unpaired student's t-test, $p<0.05$). This is in addition to the previous *in vivo* results announced in February 2020, whereby ALS-4 demonstrated on a statistically significant basis better survival rates (56% vs 0% control group) in the lethal MRSA bacteraemia rat model (Figure 3a) and higher reduction of bacterial load (by 99.5% against the control group) in the non-lethal MRSA bacteraemia rat model (Figure 3b).

Figure 3a

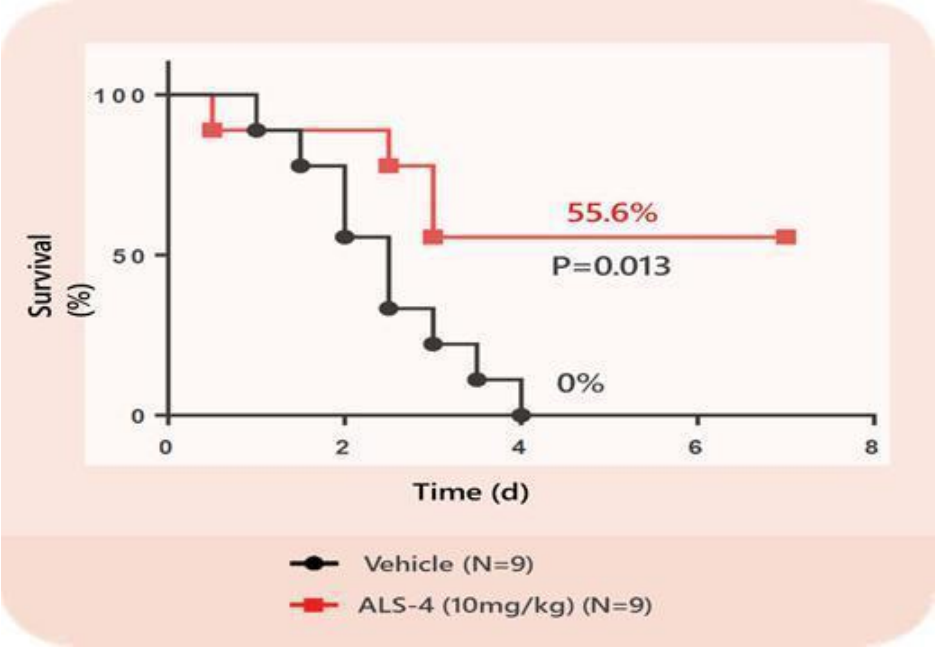


Figure 3a: Oral Formulation of ALS-4 in an MRSA Survival Study

Figure 3b

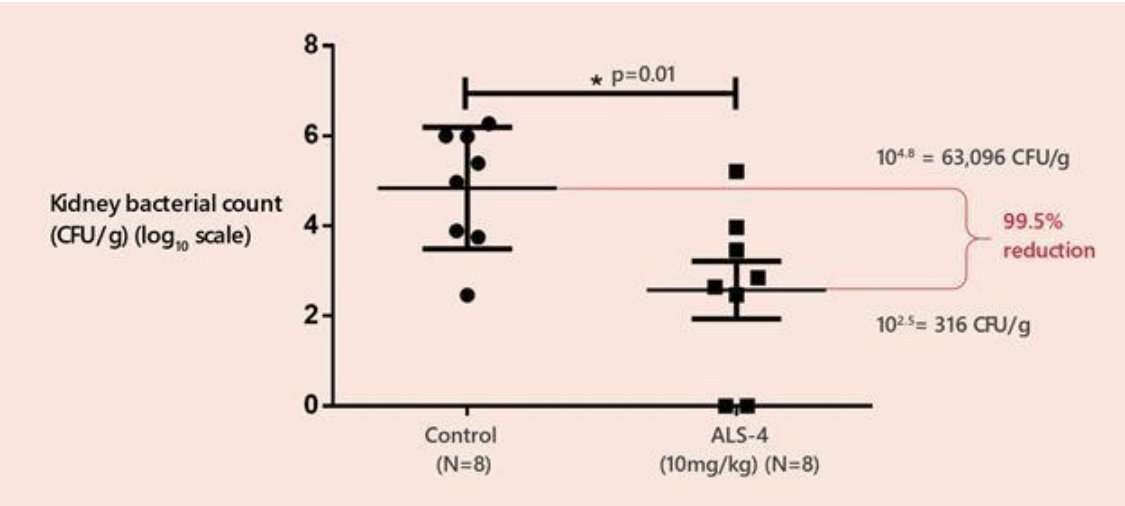


Figure 3b: Oral Formulation of ALS-4 in a Non-Lethal Bacteremia Model

CFU = Colony Forming Unit, a unit used to estimate the number of viable bacteria in a sample

A Clinical Trial Application ("CTA") was submitted with the Public Health Agency of Canada (Health Canada) to conduct a Phase 1 clinical trial of ALS-4, an orally administered small molecule drug for the treatment of infections caused by Staphylococcus aureus including Methicillin-resistant Staphylococcus aureus (MRSA) in Q4 2020. ALS-4 received clearance from Health Canada regarding the CTA to initiate a Phase 1 clinical study in January 2021. In March 2021, we announced dosing the first human subject in its Phase 1 clinical trial evaluating ALS-4. In January 2022, we further announced the completion of our Phase I clinical trial for ALS-4. The first-in-human Phase 1 trial was a randomized, double-blinded, placebo-controlled, single and multiple ascending dose study designed to evaluate safety, tolerability, and pharmacokinetics of orally administered ALS-4 in healthy male and female adult volunteers. The single-ascending dose studies (SAD) and multiple-ascending dose studies (MAD) have been completed for a total of 72 healthy subjects and no subjects were dropped from the studies. There were no serious adverse events observed and no relevant clinical changes in respect of vital signs. In March 2023, we announced the completion of the Pre-IND discussions with the US FDA. The Pre-IND discussions focused on overall development plan in preparation for the IND application of ALS-4 targeting Acute Bacterial Skin and Skin Structure Infections (ABSSSI) initially.

With the positive feedback on the overall development strategy from the US FDA, we may proceed towards the IND submission of ALS-4 seeking to initiate a Phase 2 clinical study to assess the efficacy of ALS-4 in patients in 2025.

Patent License

On October 18, 2017, the Company's subsidiary, Acticule, entered into an exclusive license agreement with Versitech Limited, the licensing entity of HKU, for ALS-4. Subsequently on June 7, 2018, the parties entered into a first amendment to the exclusive license agreement, and on July 10, 2019, the parties entered into a second amendment to the license agreement.

On January 11, 2019, Acticule and Versitech Limited entered into a second license agreement for ALS-4, where Acticule exclusively licensed the intellectual property rights on certain HKU-owned improvements to the original licensed invention.

Under the exclusive license agreements, we were granted an exclusive, royalty-bearing, sublicensable licenses to develop, make, have made, use, sell, offer for sale and import products that are covered by the licensed patents (as described below). The territory of the licenses is worldwide and the field of the licenses is for treatment or prevention of bacterial infections caused by Staphylococcus aureus including MRSA and bacterial virulence.

We paid an upfront fee upon entering into the license agreements. We are required to pay less than 10% of the net sales of the licensed products sold by us or our affiliates as royalties, as well as a low teens percentage of sublicense royalties that we receive from our sublicensees, if any. In addition, we agreed to pay to the licensor aggregate regulatory milestones of up to US$1 million subject to the following achievements: submission of investigational new drug application; completion of phase 1, 2 and 3 clinical trials; and submission of new drug application; grant of regulatory approval. We also agreed to pay to the licensor aggregate sales milestones of up to US$7.8 million subject to the following achievement: first commercial sale; and annual net sales exceeding US$100 million in one jurisdiction.

Pursuant to the license agreements, Acticule became the exclusive licensee of 2 pending U.S. non-provisional patent applications and 2 PCT applications (now expired). Prior to the expiration of the PCT applications, we filed national phase applications in member states of the PCT including Europe, PRC and 12 other jurisdictions. The claimed inventions are described as: "Compounds Affecting Pigment Production and Methods for Treatment of Bacterial Diseases."

Four (4) US patents, two (2) PRC patents, two (2) Japanese patents, and two (2) Israeli patents have been granted by various patent offices respectively.

Acticule has the right to grant sublicenses to third parties under the license agreements without prior approval from Versitech Limited and to assign the agreements to any successor to the business related to the licenses. In the event that Acticule makes an improvement to the licensed technologies, so long as the improvement does not incorporate any licensed patents, Acticule will be the owner to such improvement, subject to a non-exclusive royalty-free license being granted back to Versitech Limited for academic and research purposes only.

The exclusive license agreements shall be in effect until the expiration of all licensed patents (please refer to the patent expiration dates under "Item 4. Information on the Company – B. Business Overview – Intellectual Property"). Acticule may terminate the licenses at any time with 6-month written notice in advance. Either party may terminate the agreements upon a material breach by other party.

SACT-1: A Repurposed Drug for the Treatment of Neuroblastoma

Drug repurposing is a strategy for identifying new indications for approved or investigational drugs that are outside the scope of the original medical uses. It is often viewed as a lower-cost method for drug commercialization, as it is based on already-approved drugs (which has been proven to be safe for human use by the respective governing regulatory agency) and explores new target indications. (Ashburn, T. T. & Thor, K. B. Drug repositioning: identifying and developing new uses for existing drugs. Nat. Rev. Drug Discov. 3, 673–683, 2004).

One of the advantages of drug repurposing is a lower development risk due to safety and toxicity, as well as other properties related to water solubility, absorption, distribution and metabolism, as the safety and CMC profiles of marketed drugs are usually well-established. Due to the same reason, the development time is also shortened because there is no need to repeat the whole spectrum of the safety assessment. As a result, the drug repurposing approach appears to be attractive due to its superior risk management, smaller capital investment and quicker financial return. (Sudeep Pushpakom, et. al. Drug repurposing: progress, challenges and recommendations. Nat. Rev. Drug Discov. 18, 41-58, 2019)

The cost of bringing a repurposed drug is estimated to be around US$300 million, which is only one-tenth of the development cost for a new drug. (Nosengo, N. Can you teach old drugs new tricks? Nature. 534, 314-316, 2016).

In summary, drug repurposing offers the following advantages:

- Well-established safety profiles: The development risk for new indications can be substantially reduced by applying existing drugs that are approved or have been shown to be safe in large scale late-stage trials. Since safety accounts for approximately 30% of drug failures in clinical trials, this is a key advantage that repositioned drugs can harness to great effect. (The benefits of drug repositioning. (n.d.). Retrieved from https://www.ddw-online.com/the-benefits-of-drug-repositioning-1779-201104/)

- Time-saving: As repositioned drugs can rely on existing data, including efficacy and toxicity studies, the process is usually faster than de novo development. Developing a new chemical entity (NCE) can take 10 to 17 years, depending on indications. (Roin, B. N. Solving the Problem of New Uses, 2013). For a drug repositioning company, the development process from compound identification to launch can be around 3 to 8 years. (Walker, N. (2017, December 07). Accelerating Drug Development Through Repurposing, Repositioning and Rescue. Retrieved from https://www.pharmoutsourcing.com/Featured-Articles/345076-Accelerating-Drug-Development-Through-Repurposing-Repositioning-and-Rescue/)

- Cost-saving: Along with time-saving, money-saving is also a key benefit. The cost to relaunch a repositioned drug averages $8.4 million, whereas to relaunch a new formulation of an existing drug in its original indication costs an average $41.3 million. Given that the average cost of launching a new chemical entity (NCE) is more than $1.3 billion, successfully bringing a repositioned drug to market seems to cost approximately 160 times less than the current standard of NCE development. Even if this differential is off by a hundred times or more, from the purely financial perspective, repositioning is in a completely different league of investment needed to create a new drug product in the market. (https://www.ddw-online.com/the-benefits-of-drug-repositioning-1779-201104/)

- Potential for out-licensing: Pharmaceutical companies are said to be exploring new models to out-license some of their clinical drug candidates that may have been shelved for pure business reasons unrelated to safety or efficacy, even though they have met their endpoints and have proven themselves to be safe. If such drugs were to be repositioned, the pharmaceutical company increases the attractiveness of these drugs and gives itself more options to find interested buyers. (https://www.ddw-online.com/the-benefits-of-drug-repositioning-1779-201104/)

- Lower failure rate: According to BCC Research, approval rates for repurposed drugs are close to 30%, which is greater than the approval rate for new drug applications. (Front Oncol. 2017; 7: 273)

One of the major limitations of the current drug repurposing and repositioning practice is that there is a lack of a systematic way to identify and reinvestigate drugs that are approved and/or have failed approval.

SACT-1 is the first repurposed drug candidate to be developed under the Smart-ACT® drug discovery platform. SCAT-1 is one of the Company's proprietary technologies. Our first targeted indication is neuroblastoma. Neuroblastoma is a rare form of cancer, and classified as an orphan disease, that forms in certain types of nerve tissue and most frequently in the adrenal glands as well as spine, chest, abdomen or neck, predominantly in children, especially for those aged 5 years and below. For the high-risk group, which is close to 20% (Annu Rev Med. 2015; 66: 49–63.) of total new patient population per year, the 5-year survival rate of this condition is around 40-50% as observed by the American Cancer Society (https://www.cancer.org/cancer/neuroblastoma/detection-diagnosis-staging/survival-rates.html). The current high drug treatment cost for high risk patients can average USD200,000 per regimen (all 6 cycles) (https://www.cadth.ca/sites/default/files/pcodr/Reviews2019/10154DinutuximabNeuroblastoma_fnEGR_NOREDACT-ABBREV_Post_26Mar2019_final.pdf). In addition, most pediatric patients often do not tolerate or survive the relevant chemotherapy stage which, subject to further clinical studies, may be positively addressed by the SACT-1 candidate due to the potential synergistic effects when applied with standard chemotherapy.

In our studies, SACT-1 has been shown to be effective against numerous neuroblastoma cell lines, of which 2 are MYCN-amplified cells, which represent the high-risk neuroblastoma patient group. In addition, by using a bliss score as a quantitative measure of the extent of drug interaction, Aptorum Group has seen a high and robust synergism between SACT-1 and traditional chemotherapy in vitro (Figure 4), indicating a potential efficacy enhancement/dose reduction of the chemotherapy.

Figure 4

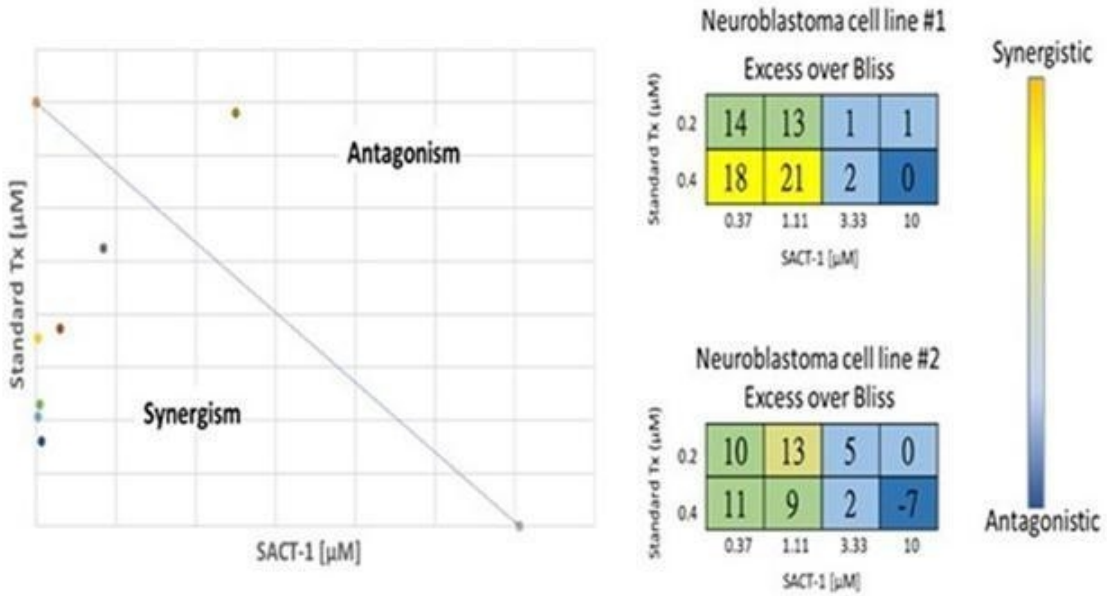


Figure 4: synergism between SACT-1 and traditional chemotherapy in vitro

In addition, in our study, the maximum tolerable dose of SACT-1 in a rodent model was determined to be higher than 400mg/kg. Compared with the MTD of standard chemotherapy such as paclitaxel (20-30mg/kg) (Clin Cancer Res. 5(11):3632-8) and cisplatin (6mg/kg) (BMC Cancer 17: 684 (2017)), the safety profile of SACT-1 appears to be very impressive. Based on our internal observations of pre-existing information from approved products, (subject to FDA's approval and on a case-by-case basis, a 505(b)(2) Application can rely in part on existing information from approved products (such as the FDA's previous findings on safety and efficacy) or products in literature (such as data available). However, typically speaking, the applicant is nonetheless required to carry out a Phase 1 bridging study to compare the Reference Listed Drug and reference the established safety and efficacy information), SACT-1 also exhibits a well-established safety profile: at 150mg/day, the death rate was 0% in prior clinical studies with no dosage related adverse events (Table 1). In addition, the pharmacokinetic profile of SACT-1 has also been reported (Table 2).

Table 1: Safety Profiles of SACT-1 in Human Clinical Trials

SACT-1	25mg/day (N=93)	75mg/day (N=95)	150mg/day (N=91)
Median treatment duration, weeks	101	100	100
Adverse events (AE)			
Any grade 2-4 AE at least possibly related to SP055	20%	20%	21%
AEs leading to discontinuation	9%	12%	14%
Any serious AE	13%	14%	10%
Deaths	0%	2%	0%

Table 2: The pharmacokinetic Profile of SACT-1 in Humans

SCAT-1 pharmacokinetic parameter in humans	(N=19)
t_{max}, h	5
C_{max}, ng/ml	~300
AUC_{last}, ng·h/ml	~10,000
AUC_{inf}, ng·h/ml	~11,000
$t_{1/2,term}$, h	~48

We have developed a pediatric formulation of SACT-1 to better address the needs of neuroblastoma patients who are exclusively children younger than 5. Positive data from our latest internal *in vivo* studies show significant activity against neuroblastoma tumor reduction when treated with the compound SACT-1 in combination with standard of care (SOC) chemotherapy.

Separately, we also screened SACT-1 for its *in vitro* activity against over 300 cancer cell lines and showed positive results in a number of cancer types including in particular colorectal cancer, leukemia and lymphoma, etc. Similar to our previous findings against neuroblastoma cell lines, SACT-1 exhibits similar anti-tumor efficacy across one or more other major cancer types, including but not limited to colorectal cancer, leukemia and lymphoma cell lines. As a result, in addition to treating neuroblastoma, SACT-1 may have potential applications in the treatment of other cancers. Based on this discovery, we plan to carry out further *in vivo* studies to study the efficacy of SACT-1 over other types of cancers to maximize the potential of SACT-1. Based on the initial 22 day data of a recent study we conducted in a xenograft mouse model of neuroblastoma, SACT-1 was orally administered daily at 60mg/kg in combination of SOC chemotherapy brought a statistically significant tumor shrinkage (unpaired student's t-test, $p<0.01$) from Day 15 to Day 22, compared to the control group which received SOC only. The combination reduced the tumor size by up to 54.2% in the first 22 days compared with the control (SOC only). SACT-1 appears to be effective in accelerating the effect of the SOC in early time points (from Day 1 - 7 vs control). This further supports our earlier *in vitro* observation that SACT-1 promotes tumor DNA damage and tumor cell death.

Figure 5

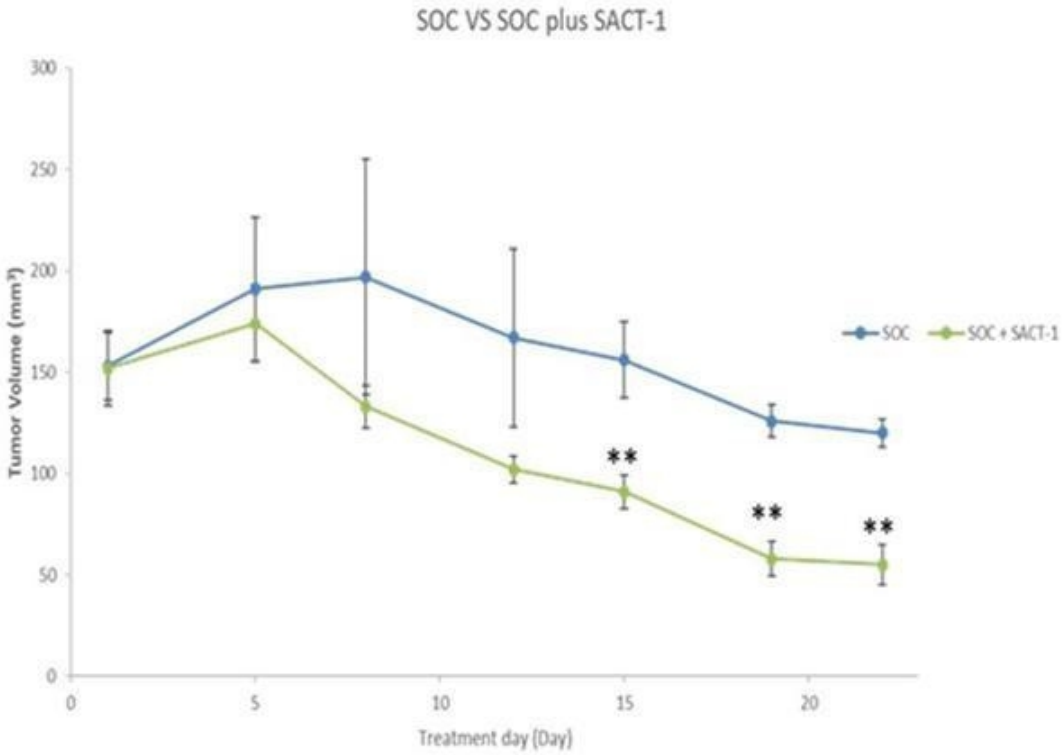


Figure 5: 22 days data of *in vivo* studies in a xenograft mouse model of neuroblastoma

** Unpaired student's t-test, $p<0.01$, n=8 (based on initial 22 days period)

In September 2021, we announced that we received clearance from the US FDA regarding the IND application to initiate clinical trials of SACT-1. In January 2022, we further announced that the completion of our Phase I clinical trial for assessing relative bioavailability and food effect of SACT-1, and no serious adverse events were observed. SACT-1's Phase 1 clinical trial is an Open-label Randomized, Single Cross Over Bioavailability and Food Effect Study of SACT-1 in healthy adult volunteers. In additions, the US FDA has granted Orphan Drug Designation to SACT-1 in January 2022. In March 2023, we further announced the completion of the End of Phase 1 (EOP1) meeting with the US FDA on SACT-1. The EOP1 meeting was focused on gaining alignment with the US FDA regarding the clinical and regulatory pathway for SACT-1 for the treatment of neuroblastoma in pediatric patients aged 2-18. The FDA generally agreed with the chemistry-manufacturing-control (CMC) strategy and our proposed clinical development plan for Phase 1/2 trials.

We may submit an IND application to the US FDA seeking to initiate our planned Phase 1b/2a trial for SACT-1 in 2025.

Patent License

In January 2022, the US Patent and Trademark Office has granted the first patent regarding Aptorum's SACT-1 (through Aptorum's subsidiary) repurposed drug for the treatment of various cancers including but not limited to neuroblastoma (US Patent 11,166,952). Another US patent (US Patent 11,571,422) was granted in February 2023, and altogether the SACT-1 patent portfolio has four (4) active national phase patent applications all over the world.

Paths^{Dx} Test: A novel molecular-based rapid pathogen identification and detection diagnostics technology

Infectious disease diagnostic standard of care (SOC) often involves techniques that are slow (e.g., bacterial culturing takes several days) or expensive (e.g., current pathogen diagnostic sequencing solutions are not comprehensive, are expensive, and often inaccessible to physicians). Although infectious disease diagnosis capabilities have been improving in recent years, there are still issues with the public health capacity to control infectious disease threats.

Infectious disease diagnostic standard of care (SOC) does not necessarily provide the physician a comprehensive diagnosis or report. Most point of care diagnostic solutions, while rapid, screen only for a single pathogen and only focus on common and widespread pathogens (e.g., HIV). Thus, for infectious disease patients in developed nations that present with an uncommon, novel or emerging pathogen threat, diagnosis is often slow (2-5 days) and inconclusive leaving time for pathogen spread and increased patient suffering and/or death.

Paths^{Dx} Test is a rapid infectious disease diagnostic test that we believe will be potentially able to identify all pathogens in a patient's sample, both known and unknown, by employing Next Generation Sequencing (NGS). The goal of Paths^{Dx} Test is to cost-effectively return a 99% accurate result within 24-48 hours. Our internal results show that, in principle, Paths^{Dx} Test can identify pathogens such as viruses (e.g. COVID-19/SARS-CoV-2) or any other known or emerging infectious disease event in one test (e.g., DNA or RNA-based pathogens). With these properties, Paths^{Dx} Test is expected to track the infectome landscape (e.g., tracking mutations), rapidly identify antibiotic resistant microbials in the process, and be more affordable than current NGS-based diagnostic platforms, which will make it a superior product to those currently on the market.

Preliminary data from our internal studies, which have not been verified or confirmed by third parties, presented below demonstrate additional points of innovation and proof of concept feasibility data.

Case Study #1: We examined a bio banked blood sample from a patient with a diagnosed Hepatitis B infection (Figure 6). Our technology successfully detected the presence of Hepatitis B, as well as additional pathogens.

Figure 6

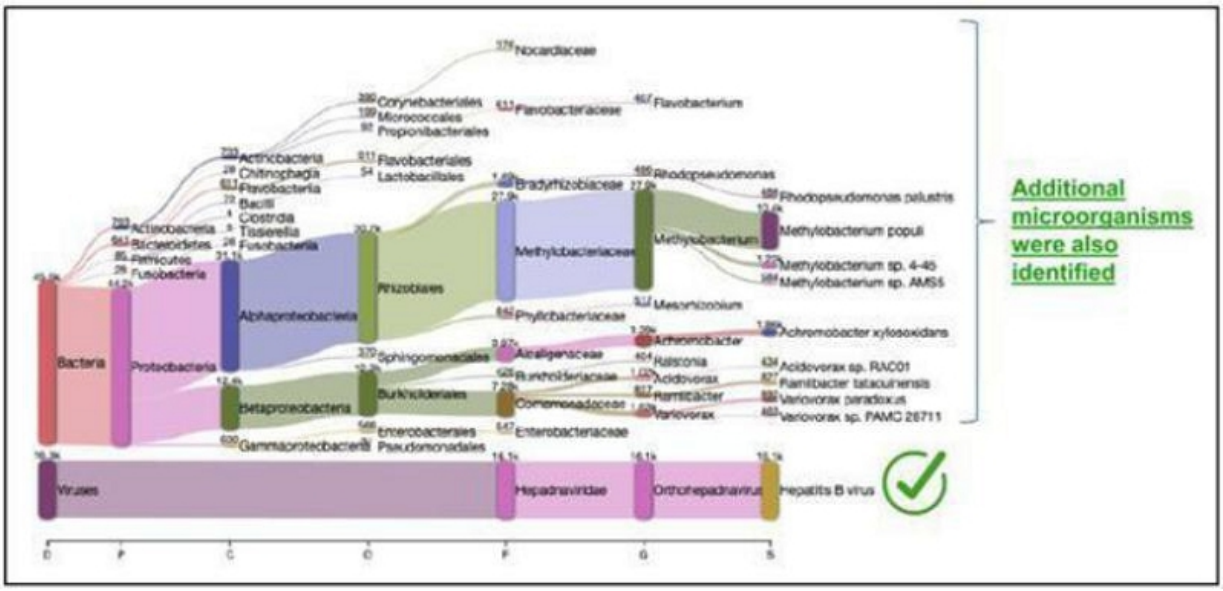


Figure 6: Aptorum's technology successfully confirmed a known Hepatitis B diagnosis in a bio banked sample.

Case Study #2: A patient was undergoing chemotherapy and developed a severe lung infection that was refractory to first-line antibiotics but eventually responded to the traditional trial and error approach. Using our technology, we found that 10% of all reads came from Leuconostoc, a Gram+ bacteria (Figure 7). Importantly, Leuconostoc was not identified by physicians, demonstrating that our technology can identify pathogens that allude a traditional diagnosis.

Figure 7

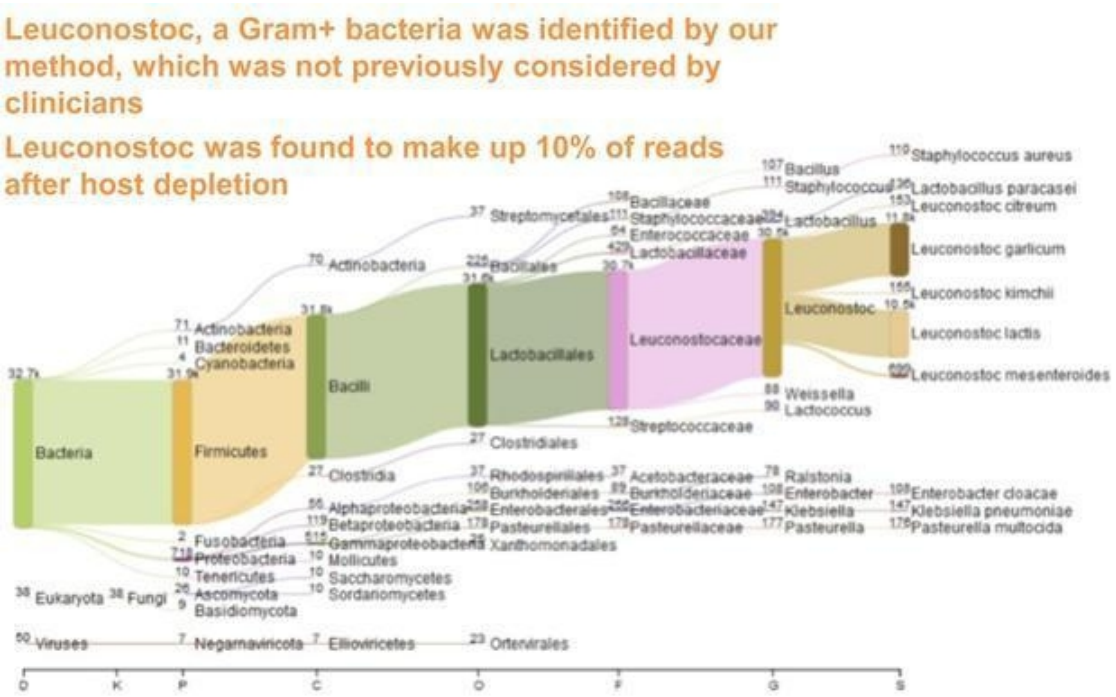


Figure 7: Aptorum's technology identified pathogen(s) that allude the traditional diagnostic approach.

Paths^{Dx} Test has the revolutionary potential to cover simultaneously over 1300 pathogens due to the unbiased approach in analyzing pathogen genome information and caters to patients who are infected with multi-strains of pathogen. The technology can be updated through our software analytics on an ongoing basis as further pathogenic genome sequences are updated through public databases, ensuring g that it is up-to-date on new and emerging pandemic threats.

Paths^{Dx} Test is currently undergoing Clinical Validation to confirm the performance of Paths^{Dx} Test using clinical/patient samples. Paths^{Dx} Test commenced clinical validations and will continue to undergo validations in parallel with its pre-commercialization process.

Patent License and Application

On September 25, 2020, the Company's subsidiary, Paths Diagnostics Pte. Limited, entered into an exclusive licence agreement with Accelerate Technologies Pte Ltd, the commercialization arm of the Singapore's Agency for Science, Technology and Research ("A*STAR"), to co-develop Paths^{Dx} Test, a novel molecular-based rapid pathogen identification and detection diagnostics technology. No upfront fee or royalty on net sales is payable under the license agreements, although we are required to pay a mid-teens to mid-twenties percentage of sublicense revenue that we receive from our sublicensees, if any. In addition, we agreed to pay to the licensor aggregate development milestones of up to US$250,000. When specific development milestone is reached, we are also required to satisfy certain diligence obligations, including recruitment of staff, establishment of relationship with potential customers and exercise commercially reasonable efforts in selling the Licensed Products.

Two (2) US provisional patent applications and one (1) Singapore patent application was filed in 2021, but subsequently abandoned. In addition, one (1) US non-provisional patent application was filed on October 8, 2021 and we filed two (2) Paris Convention (PCT) applications on February 24, 2022, and January 7, 2023, respectively. Prior to the expiration of the first PCT applications, we filed national phase applications in 12 member states including Europe, PRC, Japan, Korea and eight (8) other jurisdictions. The claimed inventions are described as: "Unbiased And Simultaneous Amplification Method For Preparing A Double-Stranded DNA Library From A Sample Of More Than One Type Of Nucleic Acid" and "Method of Degrading Nucleic Acids and Associated Compositions." Altogether, the Paths^{Dx} patent portfolio has five (5) US patents, one (1) European patent and one (1) Great Britain patent granted.

Statistical Significance

The term statistical significance is to define the probability that a measured difference between two groups (e.g. two treatment groups, treatment versus control groups) is the result of a real difference in the tested variations and not the result of chance. It means that the result of a test does not appear randomly or by chance, but because of a specific change that is tested, so it can be attributed to a specific cause.

The confidence level indicates to what percentage the test results will not commit a type 1 error, the false positive. A false positive occurs when a change in the result is due to randomness (or other noise) and not the change in variations. At a 95% confidence level ($p = 0.05$), there is a 5% chance that the test results are due to a type 1 error. 95% has become the standard and usually be the minimum confidence level for the tests. To make the test more stringent, a 99% confidence level ($p = 0.01$) is also commonly employed, which means that there is a 1% chance that the test results are due to a type 1 error.

In other words, a p value represents the confidence level. For example, if the p-value for a test is < 0.05, it means that there is less than 5% chance the difference between two groups is due to random error or by chance. If the p-value is < 0.01, it means that there is less than 1% chance the difference between two groups is due to random error or by chance.

We employed statistical testing to compare different treatment groups in animal studies simply for proof of concept and to aid internal decision making for further development. We do not intend to use this standard for any regulatory submission. The US FDA or other regulatory agencies may not necessarily employ the same statistical standard to assess the efficacy in clinical trials, the results of which would be submitted for regulatory approval. Although a p-value of 0.05 has become the standard, the US FDA or other regulatory agencies may also individualize their efficacy standard for different clinical programs based on the indications, the purpose of a clinical trial, among others.

FDA Application Status

As of the date of this the annual report, we received CTA and IND approvals for ALS-4 and SACT-1 from Health Canada and the US FDA to initiate human clinical trial. We have not submitted other applications for IND to the FDA or other regulatory agencies.

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our development and commercialization experience, scientific knowledge and industry relationships provide us with competitive advantages, we face competition from pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, and generic drug companies, academic institutions, government agencies and research institutions.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the diagnosis and treatment of diseases for which we are developing products or technology. Moreover, a number of additional drugs are currently in clinical trials and may become competitors if and when they receive regulatory approval.

Many of our competitors have longer operating histories, better name recognition, stronger management capabilities, better supplier relationships, a larger technical staff and sales force and greater financial, technical or marketing resources than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current drug candidates, or any future drug candidates we may develop, or obtain regulatory approval for their products more rapidly than we may obtain approval for our current drug candidates or any such future drug candidates. Our success will be based in part on our ability to identify, develop and manage a portfolio of drug candidates that are safer and more effective than competing products.

Inflation

Inflation affects us by generally increasing our cost of labor and research and development costs, the way it does to all labor and research costs. However, we do not anticipate that inflation will materially affect our business in the foreseeable future.

Seasonality

We believe our operation and sales do not experience seasonality.

Employees

As of the date of this annual report, we have 1 full-time employees. Of these, 1 full-time are engaged in general and administrative functions. As of the date of this annual report, all of our employees are located in Asia. In addition, we have engaged and may continue to engage 5 independent contracted consultants and advisors to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment related work stoppages, and we consider our relations with our employees to be good.

Intellectual Property

The technologies underlying our various research and development projects are the subject of various patents and patent applications claiming, in certain instances, composition of matter and, in other instances, methods of use. Prosecution, maintenance and enforcement of these patents, as well as those on any future protectable technologies we may acquire, are and will continue to be an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. Through entering into license agreements with their owners, we have obtained exclusive rights to these patents, applications and related know-how in the U.S. and certain other countries to develop, manufacture and commercialize the products using or incorporating the protected inventions that are described in this annual report and that are expected to contribute significant value to our business. The technologies protected by these patents may also for the basis for the development of other products.

In addition to licensed intellectual property, our in-house science team has been actively developing our own proprietary intellectual property. No non-provisional patent application has yet been filed in the Company's own name for the Lead Projects. We have, however, filed a number of provisional applications to establish earlier filing dates for certain of our other ongoing researches, the specifics of which are currently proprietary and confidential.

The U.S. patent system permits the filing of provisional and non-provisional patent applications (i.e., a regular patent application). A non-provisional patent application is examined by the USPTO, and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. On the other hand, a provisional patent application is not examined for patentability, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent.

Provisional applications are often used, among other things, to establish an earlier filing date for a subsequent non-provisional patent application. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained.

The effective filing date of a non-provisional patent application is used by the USPTO to determine what information is prior art when it considers the patentability of a claimed invention. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of an earlier filed provisional patent application. As a result, the filing date accorded by the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

A provisional patent application is not eligible to become an issued patent unless, among other things, we file a non-provisional patent application within 12 months of the filing date of the provisional patent application. If we do not timely file a non-provisional patent application claiming priority to said provisional application, we may lose our priority date with respect to our provisional patent applications. Further, if any (self or by others) publication of the invention is made after such priority date, and if we do not file a non-provisional application claiming priority to said provisional application, our invention may become unpatentable.

Moreover, we cannot predict whether such future patent applications will result in the issuance of patents that effectively protect any of our product candidates or will effectively prevent others from commercializing competitive products.

We do not expect to incur material expenses in the prosecution of the provisional applications or other licensed patent applications. We expect to fund the patent costs from our cash and cash equivalents.

The value of our drug products will depend significantly on our ability to obtain and maintain patent and other proprietary protection for those products, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties.

As of the date hereof, we are the patentee of a number of provisional and non-provisional patent applications, both on our proprietarily developed projects and improvement to our in-licensed projects.

The following table sets forth a list of our patent rights under the exclusive licenses as of the date of this annual report related to our Lead Projects, ALS-4 and Paths^{Dx} Test; on the other hand, our other Lead Project, SACT-1 is a proprietary technology not subject to any license agreement:

Project Company / Project name	License Agreement	Licensor(s)	Licensee	Licensed / IP Rights	Patent Expiration Dates
Acticule / ALS-4	Exclusive Patent License Agreement, dated October 18, 2017 First Amendment to Exclusive License Agreement, dated June 7, 2018 Second Amendment to Exclusive License Agreement dated July 10, 2019 Exclusive Patent License Agreement dated January 11, 2019	Versitech Limited	Acticule Life Sciences Limited	Exclusive licensee: 4 US patents (US10471045, US11446280, US11052078, US11040949), 2 PRC patents (ZL201880048665.6, ZL201880048674.5), 2 Japanese patents (JP7232238, JP 7348893), 2 Israeli patents (271863, 271864), and 9 pending applications in other foreign jurisdictions including Canada, Europe, PRC, Korea, and US.	The licensed IP rights include granted patents in the US, PRC, Japan, Israel, and pending patent applications in 3 other foreign jurisdictions. The U.S. patents will expire in 2038-2040. Any other patents derived from the pending applications, if granted, will have a 20-year patent term from 2018.
Paths^{Dx} Test	Exclusive Patent License Agreement, dated September 25, 2020	Accelerate Technologies Pte Ltd	Paths Diagnostics Pte. Limited	Exclusive licensee: 4 U.S. patents (US7635566, US8241850, US9920355, US10472667, US11,280,028), 1 European patent (EP3224374), 1 Great Britain patent (GB2532749) and 12 pending applications in other jurisdictions including Europe, PRC, Japan, Korea, etc.	The U.S. patents will expire in 2027, 2028, 2034, 2037 and 2041 respectively. The UK patent will expire in 2034. The European patent will expire in 2035. Any other patents derived from the pending applications, if granted, will have a 20-year patent term from 2022.

Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. If appropriate, the Company may seek to extend the period during which it has exclusive rights to a product by pursuing patent term extensions and marketing exclusivity periods that are available from the regulatory authorities of certain countries (including the United States) and the EPO.

Even though the Company has certain patent rights, the ability to obtain and maintain protection of biotechnology and pharmaceutical products and processes such as those we intend to develop and commercialize involves complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date in the U.S. The scope of patent protection outside the United States is even more uncertain. Changes in the patent laws or in interpretations of patent laws in the United States and other countries have diminished (and may further diminish) our ability to protect our inventions and enforce our IP rights and, more generally, could affect the value of IP.

While we have already secured rights to a number of issued patents directed to our drug candidates, we cannot predict the breadth of claims that may issue from the pending patent applications and provisional patents that we have licensed or that we have filed. Substantial scientific and commercial research has been conducted for many years in the areas in which we have focused our development efforts, which has resulted in other parties having a number of issued patents, provisional patents and pending patent applications relating to such areas. The patent examiner in any particular jurisdiction may take the view that prior issued patents and prior publications render our patent claims “obvious” and therefore unpatentable or require us to reduce the scope of the claims for which we are seeking patent protection.

In addition, patent applications in the United States and elsewhere generally are not available to the public until at least 18 months from the priority date, and the publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to drugs similar to our drug candidates may have already been filed, which (if they result in issued patents) could restrict or prohibit our ability to commercialize our drug candidates.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other IP rights. Our ability to prevent competition for our drug candidates and technologies will depend on our success in obtaining patents containing substantial and enforceable claims for those candidates and enforcing those claims once granted. With respect to any applications which have not yet resulted in issued patents, there can be no assurance that meaningful claims will be obtained. Even issued patents may be challenged or invalidated. If others have prepared and filed patent applications in the United States that also claim technology to which we have filed patent applications or otherwise wish to challenge our patents, we may have to participate in interferences, post-grant reviews, inter parties reviews, derivation or other proceedings in the USPTO and other patent offices to determine issues such as priority of claimed invention or validity of such patent applications as well as our own patent applications and issued patents. Patents may also be circumvented, and our competitors may be able to independently develop and commercialize similar drugs or mimic our technology, business model or strategy without infringing our patents. The rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

We may rely, in some limited circumstances, on unpatented trade secrets and know-how to protect aspects of our technology. However, it is challenging to monitor and prevent the disclosure of trade secrets. We seek to protect our proprietary trade secrets and know-how, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, giving our competitors knowledge of our trade secrets and know-how, and we may not have adequate remedies for any such breach, in which case our business could be adversely affected. Our trade secrets will not prevent our competitors from independently discovering or developing the same know-how. Although our agreements with our consultants, contractors or collaborators require them to provide us only original work product and prohibit them from incorporating or using IP owned by others in their work for us, if they breach these obligations, disputes may arise as to the rights in any know-how or inventions that arise from their work.

Our commercial success will also depend in part on not infringing the proprietary rights of other parties. Although we seek to review the patent landscape relevant to our technologies on an ongoing basis, we may become aware of a new patent which has been issued to others with claims covering or related to aspects of one of our drug candidate. The issuance of such a patent could require us to alter our development plans for that candidate, redesign the candidate, obtain a license from the patent holder or cease development. Our inability to obtain a license to proprietary rights that we may require to develop or commercialize any of our drug candidates would have a material adverse impact on us.

Trademarks

As of the date of this annual report, we own trademark registrations covering the trade names and logos of Aptorum and our subsidiaries, including but not limited to “APTORUM”, “APTORUM THERAPEUTICS,” “VIDENS LIFE SCIENCES,” “ACTICULE LIFE SCIENCES,” “NATIVUS LIFE SCIENCES,” and “NATIVUSWELL” in jurisdictions such as Australia, EU, Hong Kong, the United Kingdom, US and PRC.

We also own certain unregistered trademark rights.

All other trade names, trademarks and service marks of other companies appearing in this annual report are the property of their respective holders. Solely for convenience, the trademarks and trade names in annual report are 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. We do not intend our use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Regulations

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing, export and import of drug products ("Regulated Products"), such as those we are developing. Generally, before a new Regulated Product can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized to address the requirements of and in the format specific to each regulatory authority, submitted for review and approved by the regulatory authority. This process is very lengthy and expensive, and success is uncertain.

Regulated Products are also subject to other federal, state and local statutes and regulations in the United States and other countries, as applicable. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, disbarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any such administrative or judicial enforcement action could have a material adverse effect on us.

As part of the Company's principal place of business is in Hong Kong, the Company is subject to various Hong Kong laws and regulation covering its business activities there, described in further detail below. Also, the Company anticipates that, if it obtains marketing approval for any of its drug candidates, it intends to focus its marketing and sales efforts primarily in three regions: the United States, Canada, Europe and PRC. The regulatory framework for each of these regions is described below.

U.S. Drug Development Process

The process of obtaining regulatory approvals and maintaining compliance with appropriate federal, state and local 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 administrative or judicial sanctions or lead to voluntary product recalls. Administrative or judicial sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, 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 non-clinical laboratory tests, preclinical studies according to cGLP and manufacturing of clinical supplies according to cGMP;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to cGCP, to establish the safety and efficacy of the proposed product for its intended use;
- preparation and submission to the FDA of an NDA, for a drug;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP; and
- payment of user fees and the FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our drug candidates, or any future drug candidates we may develop, will be granted on a timely basis, if at all.

Once a drug candidate is identified for development, it enters the non-clinical testing stage. Non-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as preclinical studies. An IND sponsor must submit the results of the non-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND prior to commencing any testing in humans. An IND sponsor must also include a protocol detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some non-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance, and may be imposed on all products within a certain class of products. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials for certain duration or for certain doses.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with cGCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an IRB representing each institution participating in a clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB is responsible for protecting the rights of clinical trial subjects and considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRBs for approval. Protocol detail, among other things, includes the objectives of the clinical trial, testing procedures, sublease selection and exclusion criteria, and the parameters to be used to monitor subject safety.

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

- **Phase 1.** Phase 1 includes the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in Phase 1 studies varies with the drug, but is generally in the range of twenty to eighty.

- **Phase 2.** Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people.

- **Phase 3.** Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies are designed to provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and clinical investigators within 15 calendar days for serious and unexpected suspected adverse events, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug candidate. Additionally, a sponsor must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction no later than 7 calendar days after the sponsor's receipt of the information. There is no assurance that Phase 1, Phase 2 and Phase 3 testing can be completed successfully within any specified period, or at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

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

The results of product development, non-clinical studies and clinical trials, together with other detailed information regarding the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA requesting approval to market the new drug. The FDA reviews all NDAs submitted within 60 days of submission to ensure that they are sufficiently complete for substantive review before it accepts them for filing. If the submission is accepted for filing, the FDA begins an in-depth substantive review.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

If after such review a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. Any products for which we receive the FDA approval would be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with the FDA promotion and advertising requirements. In addition, the FDA may require post-approval studies, including Phase 4 clinical trials, to further assess a product's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA also may conclude that an NDA may only be approved with a Risk Evaluation and Mitigation Strategy designed to mitigate risks through, for example, a medication guide, physician communication plan, or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Post-Approval Requirements

Any products for which we receive the FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with the FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior the FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further the FDA review and approval.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product's marketing or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, untitled or warning letters, holds on clinical trials, product seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or consent decrees, or civil or criminal penalties, or may lead to voluntary product recalls.

Patent Term Restoration and Marketing Exclusivity

Because drug approval can take an extended period of time, there may be limited remaining life for the patents covering the approved drug, meaning that the company has limited time to use the patents to protect the sponsor's exclusive rights to make, use and sell that drug. In such a case, U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date.

In addition, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) Application submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval.

In the future, if appropriate, we intend to apply for restorations of patent term and/or marketing exclusivity for some of our products; however, there can be no assurance that any such extension or exclusivity will be granted to us.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of the FDA-regulated products, including drugs are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pharmaceutical Coverage, Pricing and Reimbursement

Much of the revenue generated by new Regulated Products depends on the willingness of third-party payors to reimburse the price of the product. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which is not required to include all of the FDA-approved products for a particular indication. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Unfavorable coverage or reimbursement policies regarding any of the Company's products would have a material adverse impact on the value of that product.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval of our products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

Patient Protection and the Affordable Care Act

The Affordable Care Act, enacted in March 2010, includes measures that have or will significantly change the way health care is financed in the United States by both governmental and private insurers. Among the provisions of the Affordable Care Act of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The Affordable Care Act increased pharmaceutical manufacturers' rebate liability on most branded prescription drugs from 15.1% of the average manufacturer price to 23.1% of the average manufacturer price, added a new rebate calculation for line extensions of solid oral dosage forms of branded products, and modified the statutory definition of average manufacturer price. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and expanding the population potentially eligible for Medicaid drug benefits.

- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing.

- The Affordable Care Act imposed a requirement on manufacturers of branded drugs to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the "donut hole").

- The Affordable Care Act imposed an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications.

In addition to these provisions, the Affordable Care Act established a number of bodies whose work may have a future impact on the market for certain pharmaceutical products. These include the Patient-Centered Outcomes Research Institute, established to oversee, identify priorities in, and conduct comparative clinical effectiveness research, the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program, and the Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid Services, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

These and other laws may result in additional reductions in healthcare funding, which could have a material adverse effect on customers for our product candidates, if we gain approval for any of them. Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will use our product candidates if we gain approval for any of them.

Canadian Regulation

In Canada, our pharmaceutical product candidates and our research and development activities are primarily regulated by the *Food and Drugs Act* and the rules and regulations thereunder, which are enforced by Health Canada. Health Canada regulates, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, post-approval monitoring, marketing and import and export of pharmaceutical products. Drug approval laws require licensing of manufacturing facilities, carefully controlled research and testing of products, government review and approval of experimental results prior to giving approval to sell drug products. Regulators also typically require that rigorous and specific standards such as Good Manufacturing Practices (GMP), Good Laboratory Practices, or GLP, and Good Clinical Practices, or GCP, are followed in the manufacture, testing and clinical development, respectively, of any drug product. The processes for obtaining regulatory approvals in Canada, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

The principal steps required for drug approval in Canada is as follows:

Preclinical Toxicology Studies

Non-clinical studies are conducted *in vitro* and in animals to evaluate pharmacokinetics, metabolism and possible toxic effects to provide evidence of the safety of the drug candidate prior to its administration to humans in clinical studies and throughout development. Such studies are conducted in accordance with applicable laws and GLP.

Initiation of Human Testing

In Canada, the process of conducting clinical trials with a new drug cannot begin until we have received a NOL (No objection Letter) from Health Canada, typically within 30 days (during Covid the 30 days extended to 45 days) of a CTA submission. Similar regulations apply in Canada to a CTA as to an IND in the United States. Once approved, two key factors influencing the rate of progression of clinical trials are the rate at which patients can be enrolled to participate in the research program and whether effective treatments are currently available for the disease that the drug is intended to treat. Patient enrollment is largely dependent upon the incidence and severity of the disease, the treatments available and the potential side effects of the drug to be tested and any restrictions for enrollment that may be imposed by regulatory agencies.

Clinical Trials

Similar regulations apply in Canada regarding clinical trials as in the United States. In Canada, Research Ethics Boards, or REBs, instead of IRBs, are used to review and approve clinical trial plans. Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or cGCP, requirements, which include review and approval by REBs. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Human clinical trials are typically conducted in three sequential phases, as discussed above in similar context to government regulation in the United States.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to current Good Manufacturing Practice, or cGMP, requirements. Investigational drugs and active pharmaceutical ingredients imported into Canada are also subject to regulation by Health Canada relating to their labeling and distribution. Post authorization requirements include reporting of serious adverse events and clinical trial site inspection program. Phase 1, Phase 2 and Phase 3 clinical trials are subject to a clinical trial application (CTA) for each phase of study. Furthermore, in Canada, Health Canada or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an REB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the REB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

New Drug Submission (NDS)

Upon successful completion of Phase 3 clinical trials, in Canada the company sponsoring a new drug then assembles all the preclinical and clinical data and other testing relating to the product's pharmacology, chemistry, manufacture, and controls, and submits it to Health Canada as part of a New Drug Submission, or NDS. The NDS is then reviewed by Health Canada for approval to market the drug.

As part of the approval process, an additional application for a Drug Establishment License (DEL) 90 days prior the NDS submission to Health Canada to initiate review and inspection of the facility or the facilities at which the drug is manufactured are compliant with GMP requirements. Health Canada will not approve the product unless compliance with cGMP—a quality system regulating manufacturing—is satisfactory and the NDS contains data that provide substantial evidence that the drug is safe and effective in the indication studied. In addition, before approving an NDS, Health Canada will typically inspect one or more clinical sites to assure compliance with GCP.

The testing and approval process for an NDS requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Health Canada may not grant approval of an NDS on a timely basis, or at all. In Canada, NDSs are subject to user fees and these fees are typically increased annually to reflect inflation.

Even if Health Canada approves a product candidate, the relevant authority may limit the approved indications for use of the product candidate, require that contraindications, warnings or precautions be included in the product labeling, including a black box warning, 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 restrictions or other risk management mechanisms.

Health Canada 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, notification, and regulatory authority review and approval. Further, should new safety information arise, additional testing, product labeling or regulatory notification may be required.

European Union Regulation

Regulation in the European Union

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

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on cGCP, a system for the approval of clinical trials in the EU (the equivalent of the IND process in the United States) has been implemented through national legislation of the EU member states. Under this system, an applicant must obtain approval from the competent national authority of an EU member state in which the clinical trial is to be conducted or in multiple EU member states if the clinical trial is to be conducted in a number of EU member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application, or CTA, must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the EU member states and further detailed in applicable guidance documents.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will apply in 2019. It will overhaul the current system of approvals for clinical trials in the EU. Specifically, the new regulation, which will be directly applicable in all EU member states, aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

Marketing Authorization

To obtain a marketing authorization for a product under the EU regulatory system (the equivalent of the NDA process in the United States), an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU member states (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EU. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the EU, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established by the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Periods of Authorization and Renewals

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

Regulatory Requirements after Marketing Authorization

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

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized EU marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the EU member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

PRC Regulation

In order to protect our potential market in the PRC, we have obtained an exclusive license of certain PRC patents directed to certain of the drug candidates that we are developing and are currently seeking approval of additional patent and other IP filings in the PRC. Seeking IP approval in the PRC subjects us to some of the rules and practices of the PRC government. Since the Company intends eventually to market its products in the PRC, at least some of our drug candidates may become subject to regulatory approval and marketing authorization in the PRC.

Permission Required from the PRC Authorities

As of the date of this annual report, we are not required to obtain approvals from the PRC authorities to operate our business or list on the U.S. exchanges and offer or continue to offer securities; specifically, we are currently not required to obtain any permission or approval from the CSRC, the CAC or any other PRC governmental authority to operate our business or to list our securities on a U.S. securities exchange or issue securities to foreign investors. The laws and regulations of mainland China do not currently have any material impact on our business, financial condition or results of operations and we are currently not subject to the PRC government's direct influence or discretion over the manner in which we conduct our business activities outside of the mainland China.

Nevertheless, we are aware that recently, the PRC government initiated a series of regulatory actions and statements to regulate business operations in certain areas in mainland China with little advance notice, including cracking down on illegal activities in the securities market, enhancing supervision over mainland Chinese companies listed overseas using a VIE structure, adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement. Since these statements and regulatory actions are new, it is highly uncertain how soon the legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any. It is also highly uncertain what potential impact such modified or new laws and regulations will have on Aptorum Group's daily business operations, its ability to accept foreign investments and the listing of our Class A Ordinary Shares on a U.S. or other foreign exchange. If there is significant change to current political arrangements between mainland China and Hong Kong, the PRC government intervenes or influences operations of companies operated in Hong Kong like us, or exerts more control through change of laws and regulations over offerings conducted overseas and/or foreign investment in issuers like us, it may result in a material change in our operations and/or the value of the securities we are registering for sale or could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of our Class A Ordinary Shares to significantly decline or become worthless. (Please see the risk factor section, "Risks Related to our Corporate Structure" and "Risks Related to Doing Business in Hong Kong" for more information).

Hong Kong Regulation

The operations of laboratory in Hong Kong are subject to certain general laws and regulations.

Waste Disposal Ordinance

The Waste Disposal Ordinance (Chapter 354 of the Laws of Hong Kong) ("WDO") and the Waste Disposal (Clinical Waste) (General) Regulation (Chapter 354O of the Laws of Hong Kong) (the "WDR") provide for, among others, the control and regulation of the production, storage, collection and disposal of clinical waste.

Under the WDO, clinical waste means waste consisting of any substance, matter or thing generated in connection with:

- a dental, medical, nursing or veterinary practice;
- any other practice, or establishment (howsoever described), that provides medical care and services for the sick, injured, infirm or those who require medical treatment;
- dental, medical, nursing, veterinary, pathological or pharmaceutical research; or
- a dental, medical, veterinary or pathological laboratory practice,

and which consists wholly or partly of any of the materials specified in one or more of the groups listed below:

- used or contaminated sharps;
- laboratory waste;
- human and animal tissues;
- infectious materials;
- dressings; and
- such other wastes as specified by the Director of the Environmental Protection Department ("EPD") of Hong Kong.

Given the research works in our R&D Center may produce used or contaminated sharps such as syringes and needles as well as dressings, we are subject to WDO, WDR and the Code of Practice.

Rest of the World Regulation

For other countries in the world, the requirements governing the conduct of clinical trials, medical product licensing, pricing and reimbursement vary from country to country. In all cases if clinical trials are required, they must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

C. Our Structure

See "Item 4. Information on the Company – A. History and Development of the Company."

D. Property, plants and equipment

We have an operating lease for laboratory in Hong Kong, with 2,021 square feet lab space under a lease that commenced in March 2020, renewed in March 2023 and expires in March 2026. The monthly rent ranges from $6,348 to $9,068. Payments under operating leases are expensed on a straight-line basis over the periods of the respective leases, and the terms of the leases do not contain contingent rent and renewal or purchase options.

We believe our current facilities are sufficient to meet our needs.

Item 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion of our financial condition and results of operations is based upon and should be read in conjunction with our consolidated financial statements and their related notes included in this annual report.

For purposes of Item 5, reference to the "We", "Our", "Ours" or "Group" means Aptorum Group Limited and all of its subsidiaries.

This annual report includes consolidated financial statements for the years ended December 31, 2024, 2023, and 2022. However, as permitted by Instruction 6 to Item 5 of Form 20-F, a discussion of the changes in our results of operations for the years ended December 31, 2022, and 2021 has been omitted from this annual report, but may be found in "Item 5. Operating And Financial Review And Prospects" in our annual report on Form 20-F for the year ended December 31, 2022, filed with the SEC on April 28, 2023.

This annual report contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to us. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify these forward-looking statements by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, among other things, statements relating to:

- our goals and strategies;
- our future business development, financial conditions and results of operations;
- our expectations regarding demand for and market acceptance of our products once available;
- our expectations regarding our development and commercialization of our therapeutics;
- competition in our industry; and
- relevant government policies and regulations relating to our industry.

You should thoroughly read this annual report and the documents that we refer to in this annual report with the understanding that our actual results in the future may be materially different from or worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements. Other sections of this annual report include additional factors which could adversely affect our business and financial performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in "Item 3. Key Information—D. Risk Factors" and elsewhere in this annual report. We caution you that our businesses and financial performance are subject to substantial risks and uncertainties.

The forward-looking statements made in this annual report relate only to events or information as of the date on which these statements are made in this annual report. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this annual report. You should not rely upon forward-looking statements as predictions of future events.

A. Operating Results

Overview

We are a clinical stage biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutic assets to treat diseases with unmet medical needs, particularly in oncology (including orphan oncology indications) and infectious diseases. The pipeline of Aptorum is also enriched through the co-development of Paths^{Dx} Test, a novel molecular-based rapid pathogen identification and detection diagnostics technology, with Accelerate Technologies Pte Ltd, commercialization arm of the Singapore's Agency for Science, Technology and Research.

The Company now focuses all of its efforts on R&D and therefore no longer performs any therapeutic services. While the Company may commence therapeutic services in the future, as of December 31, 2024 and the date hereof, it only operates in one segment.

Based on our evaluation of preliminary data and our consideration of a number of factors including substantial unmet needs, benefits over existing therapies, potential market size, competition in market, the Company decides how to prioritize its resources among projects. Overall, our rationale for selecting Lead Projects is not based on any mechanical formula or rigid selection criteria, but instead focused on a combination of the factors and individual attributes of the Lead Projects themselves. See "Item 3. Key Information—D. Risk Factors— Risks Related to the Preclinical and Clinical Development of Our Drug Candidates— "Preclinical development is a long, expensive and uncertain process, and we may terminate one or more of our current preclinical development programs." and "Management has discretion to terminate the development of any of our projects at any time."

Our goal is to develop a broad range of novel and repurposed therapeutics and diagnostics technology across a wide range of disease/therapeutic areas. Key components of our strategy for achieving this goal include: (for details of our strategy, See "Item 4. Information on the Company – B. Business Overview – Our Strategy")

- Developing therapeutic and diagnostic innovations across a wide range of disease/therapeutic areas;
- Selectively expanding our portfolio with potential products that may be able to attain orphan drug designation and/or satisfy current unmet medical needs;
- Collaborating with leading academic institutions and CROs;
- Expanding our in-house pharmaceutical development center;
- Leveraging our management's expertise, experience, and commercial networks;
- Obtaining and leveraging government grants to fund project development.

We have devoted a substantial portion of the proceeds from our offerings to our Lead Projects. Our Lead Projects are ALS-4, SACT-1 and Paths^{Dx} Test. In March 2023, we announced that we completed the Pre-IND discussions with the US FDA on ALS-4. With the positive feedback on the overall development strategy from the US FDA, we are proceeding towards the IND submission of ALS-4. In March 2023, we also announced the completion of the End of Phase 1 (EOP1) meeting of SACT-1 with the US FDA. The FDA generally agreed with the chemistry-manufacturing-control (CMC) strategy and our proposed clinical development plan for SACT-1 Phase 1/2 trials. We commenced clinical validation of our molecular based Paths^{Dx} Test and will continue to undergo validations in parallel with its pre-commercialization process.

During the second quarter of 2023, the Company made a decision to streamline its operations by terminating clinic services and suspending non-lead R&D projects. This measure is aimed at optimizing the allocation of our resources and focusing our efforts on advancing our lead projects, which hold the most promise for commercial success and beneficial impact. This decision aligns with our commitment to enhance shareholder value and effectively drive our core objectives forward in the competitive landscape.

Proposed Merger and Subsequent Termination of Merger Agreement

On March 1, 2024, we entered into an Agreement and Plan of Merger with YOOV Group Holding Limited, a company organized under the laws of British Virgin Islands ("YOOV"), pursuant to which YOOV was to become one of our wholly owned subsidiaries. However, on October 25, 2024, the parties to the Agreement and Plan of Merger entered into a termination agreement (the "Termination Agreement"), pursuant to which the parties agreed to terminate the Agreement and Plan of Merger on the date thereof (the "Termination Date"), and such agreement became null and void and of no further force or effect.

At the Market Offering

On March 26, 2021, the Company entered into an at the market offering agreement (the "Sales Agreement"), with H.C. Wainwright & Co., LLC, acting as our sales agent (the "Sales Agent"), relating to the sale of our Class A Ordinary Shares, offered pursuant to the prospectus supplement and the accompanying prospectus to the registration statement on Form F-3 (File No. 333-268873) (such offering, the "ATM Offering", or "At The Market Offering"). In accordance with the terms of the Sales Agreement, we may offer and sell shares of our Class A Ordinary Shares having an aggregate offering price of up to $15,000,000 from time to time through the Sales Agent under such prospectus supplement and the accompanying prospectus. As of the date of this annual report, we have issued 215,959 Class A Ordinary Shares pursuant to the ATM Offering.

Registered Direct Offering

On January 2, 2025, the Company entered into a certain securities purchase agreement (the "Securities Purchase Agreement") with certain non-affiliated institutional investors pursuant to which the Company sold 1,535,000 Class A ordinary shares of the Company, par value $0.00001 per share at a per share price of $2.00 in a registered direct offering, for gross proceeds of $3,070,000 (the "Offering").

The Company agreed in the Securities Purchase Agreement that, subject to certain exceptions, for thirty (30) calendar days following the closing of the Offering (the "Standstill Period"), it would not (i) issue, or enter into any agreement to issue or announce the issuance or proposed issuance of any Ordinary Shares, or any securities of the Company or its subsidiaries which would entitle the holder thereof to acquire at any time Ordinary Shares (the "Ordinary Share Equivalents"), or (ii) file any registration statement or amendment or supplement thereto, other than the Prospectus Supplement contemplated in the Securities Purchase Agreement and the filing of a registration statement on Form S-8 in connection with any employee benefit plan. In addition, during the Standstill Period, subject to certain exceptions, the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of Ordinary Shares or Ordinary Share Equivalents (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the Securities Purchase Agreement).

Private Placement Offerings

Sales of convertible notes

On December 9, 2022, the Company entered into a securities purchase agreement with Aenco Technologies Limited ("Aenco"). Pursuant to the securities purchase agreement, Aenco is purchasing a convertible note in the original principal amount of $3,000,000 (the "Dec 2022 Note"). The Dec 2022 Note is unsecured, convertible into the Company's restricted Class A Ordinary Shares at Aenco's option. The Dec 2022 Notes have a maturity date of 12 months subject to the Aenco's extension, a bullet interest rate of 7% per annum, and a conversion price of $12.00 per Class A Ordinary share. The Company shall have an obligation to repay the principal amount and interest of the Dec 2022 Note on the maturity date in cash or in unregistered Class A Ordinary Shares or a combination of such at the Company's discretion. In April 2023, Aenco transferred the whole Dec 2022 Note to two external investors, and the two external investors fully converted the Dec 2022 Note into 250,000 Class A Ordinary Shares.

On June 28, 2023, the Company entered into a securities purchase agreement with 4 investors. Pursuant to the securities purchase agreement, the investors are purchasing a convertible note in the original principal amount of $3,000,000 (the "June 2023 Note"). The whole proceeds from the June 2023 Note were used to settle a related party loan. The June 2023 Note is unsecured, convertible into the Company's restricted Class A Ordinary Shares at the Note holder option. The June 2023 Notes have a maturity date of 12 months subject to the investors extension, a bullet interest rate of 7% per annum, and a conversion price of $3.00 per Class A Ordinary share. The Company shall have an obligation to repay the principal amount and interest of the June 2023 Note on the maturity date in cash or in unregistered Class A Ordinary Shares or a combination of such at the Company's discretion. Immediately following the issuance of June 2023 Note, the June 2023 Note was fully converted into 1,000,000 Class A Ordinary Shares.

On September 11, 2023, the Company entered into a Securities Purchase Agreement with Jurchen Investment Corporation, the largest shareholder of the Company, pursuant to which the Company sold a secured convertible note in the aggregate principal amount of $3,000,000 (the "Sep 2023 Notes"). The Sep 2023 Notes are convertible into the Company's Class A Ordinary Shares and have a maturity date that is 24 months from the issuance date, although upon such date the investor has the right to extend the term of the Sep 2023 Note for twelve (12) months or more or such term subject to mutual consent. The Sep 2023 Notes have an interest rate of 6% per annum and a conversion price of $2.42 per share. The Company has the right to repay the principal amount of the Sep 2023 Notes, but in the case of such prepayment it must be paid in cash, unless otherwise agreed by both parties. The Sep 2023 Note is secured by a first priority lien and security interest on certain shares that the Company owns ("Collateral"). Upon the Company's disposal of all or a portion of the Collateral, the investor has the right, to request that the Company prepay the then-remaining outstanding balance of the Sep 2023 Note, in part or in full and the Company can make that payment in cash or in shares.

Legal Proceedings

On December 16, 2024, the Company received a letter from Carey Olsen with a Summons with Notice dated September 3, 2024, taken out by Karen Cheung (a/k/a Wing TSZ Cheung) as plaintiff against, among others, the Company as defendant in the Supreme Court of the State of New York County of New York, in relation to an action to recover financial losses sustained by the plaintiff (the "Case"). The Case is at the very early stages of litigation and although we intend to defend the lawsuit, there can be no assurance regarding the ultimate outcome of this case. Due to the inherent uncertain nature of litigation, the ultimate outcome or actual cost of settlement may materially vary from estimates. If management's estimates prove incorrect, current reserves could be inadequate and we could incur a charge to earnings which could have a material adverse effect on our results of operations, financial condition, net worth, and cash flows.

Factors Affecting our Results of Operations

Research and Development Expenses

We believe our ability to successfully develop innovative drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Creating high quality global first-in-class or best-in-class drug candidates requires significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been steadily advancing. For more information on the nature of the efforts and steps necessary to develop our drug candidates, see Item 4.B. “Business Overview— Lead Projects, Natural Supplements and Other Projects under Development.”

Our drug candidates are still in development, and we have incurred and will continue to incur significant research and development costs for pre-clinical studies and clinical trials. We expect that our research and development expenses will significantly increase in future periods in line with the advancement and expansion of the development of our drug candidates.

Research and development expenses include:

- employee and consultant compensation related expenses, including salaries, benefits and share based compensation expenses;
- expenses incurred for payments to CROs, investigators and clinical trial sites that conduct our clinical studies;
- the cost of acquiring IP rights which did not meet the criteria of capitalization under the U.S. GAAP;
- cost associated with sponsored research programs with various universities and research institutions
- facilities, depreciation, and other expenses, which include office leases and other overhead expenses; and
- costs associated with patent applications.

Research and development expenses incurred totaled $2.2 million, $5.2 million, and $9.2 million for the years ended December 31, 2024, 2023 and 2022, respectively, representing approximately 55.7%, 46.6%, and 49.0% of our total operating expenses for the respective period.

We have been able to fund the research and development expenses for our drug candidates through a range of sources, including the proceeds raised from our public offering and follow-on offerings on Nasdaq, private placement to other investors and line of credit facilities from shareholders, related parties, and banks.

This diversified approach to funding allows us to not depend on any one method of funding for our research and development activities, thereby reducing the risk that sufficient financing will be unavailable as we continue to accelerate the development of our drug candidates.

RESULTS OF OPERATIONS

Results of Operations for the Years ended December 31, 2024, and 2023

During the second quarter of 2023, the Company made a decision to streamline its operations by terminating clinic services and suspending non-lead R&D projects. This measure is aimed at optimizing the allocation of our resources and focusing our efforts on advancing our lead projects, which hold the most promise for commercial success and beneficial impact. This decision aligns with our commitment to enhance shareholder value and effectively drive our core objectives forward in the competitive landscape.

The following table summarizes our results of operations for the years ended December 31, 2024, and 2023.

	Year Ended December 31, 2024	Year Ended December 31, 2023
Revenue		
Healthcare services income	$ -	$ 431,378
Operating expenses		
Cost of healthcare services	-	(420,812)
Research and development expenses	(2,195,161)	(5,198,329)
General and administrative fees	(669,486)	(1,930,637)
Legal and professional fees	(803,285)	(2,538,161)
Other operating expenses	(272,609)	(1,067,690)
Total expenses	(3,940,541)	(11,155,629)
Other (expense) income, net		
Loss on investments in marketable securities, net	-	(9,266)
Unrealized gain from fair value change of the long-term investments, net	-	6,431,088
Impairment loss of long-term investment	(1,000,000)	(77,200)
Interest expense, net	(146,924)	(121,145)
Gain on disposal of subsidiaries	703	-
Government subsidies	928,461	123,015
Sundry income	564	36,784
Total other (expense) income, net	(217,196)	6,383,276
Net loss	(4,157,737)	(4,340,975)

Revenue

Healthcare services income was $nil and $431,378 for the years ended December 31, 2024, and 2023, which related to the service income derived from clinic. The decline in healthcare services income was attributed to the strategic decision to suspend clinic services in the second quarter of 2023. This was done to reallocate resources towards the development of the Company's leading projects.

Cost of healthcare services

Cost of healthcare services was $nil and $420,812 for the years ended December 31, 2024, and 2023, which related to the cost incurred by clinic. The decline in cost of healthcare services was attributed to the strategic decision to suspend clinic services in the second quarter of 2023.

Research and development expenses

The following table sets forth a summary of our research and development expenses for the years ended December 31, 2024, and 2023. Before the Merger Agreement was terminated, we determined it was best to focus all of our attention and resources on completing the Merger and therefore paused the majority of our R&D activities during that time; following the termination of the Merger Agreement in the fourth quarter of fiscal 2024, we determined that searching for other business combination opportunities could maximize shareholder value, and R&D focused on non-lead products remain suspended.

	Year Ended December 31, 2024	Year Ended December 31, 2023
Research and Development Expenses:		
Contracted research organizations services	$ 166,972	$ 1,387,534
Sponsored research	39,972	17,149
Amortization and depreciation	251,567	1,071,455
Consultation	44,872	1,207,188
Loss on impairments of an intangible asset	128,128	519,497
Impairment of properties, plant and equipment	1,421,782	-
Payroll expenses	-	363,139
Other R&D expenses	141,868	632,367
Total Research and Development Expenses	$ 2,195,161	$ 5,198,329

General and administrative fees

The following table sets forth a summary of our general and administrative expenses for the years ended December 31, 2024, and 2023. The decrease in general and administrative fees was primarily attributable to the streamlining of our operations to focus on preparation for the Merger, which has since been abandoned.

	Year Ended December 31, 2024	Year Ended December 31, 2023
General and Administrative Fees:		
Payroll expenses	$ 208,348	$ 893,437
Rent and rates	97,253	213,701
Travelling expenses	205	59,874
Amortization and depreciation	3,480	53,799
Insurance	335,616	474,746
Advertising and marketing expenses	-	48,982
Write-off of prepayment and other receivables	9,782	-
Other expenses	14,802	186,098
Total General and Administrative Fees	$ 669,486	$ 1,930,637

Legal and professional fees

For the years ended December 31, 2024, and 2023, the legal and professional fees were $803,285 and $2,538,161, respectively. The decrease in legal and professional fees was primarily attributed to the lack of non-routine activities that were present in the same period last year, such as the implementation of reverse stock split, and amendments to the memorandum and articles of association. The absence of such non-routine exercises in the current period has resulted in a decrease in legal and professional fees.

Other operating expenses

For the years ended December 31, 2024, and 2023, the other operating expenses was $272,609 and $1,067,690, respectively. The decrease in other operating expenses was primarily due to the decrease in impairment loss of long-lived assets since the majority of long-lived assets were impaired in prior year and no such large impairment in current year.

Other (expense) income, net

For the years ended December 31, 2024, and 2023, the other expense, net, was $217,196 and other income, net, was $6,383,276, respectively. The changes from other income in 2023 to other expense in 2024 was mainly due to there was a one-off unrealized gain from fair value change of the long-term investments, amounted to $6.4 million in prior year, which there are no such gain in current year.

Net loss attributable to Aptorum Group Limited

For the years ended December 31, 2024, and 2023, net loss attributable to Aptorum Group Limited (excluding net loss attributable to non-controlling interests) was $4,267,806 and $2,824,647, respectively.

Results of Operations for the Years ended December 31, 2023, and 2022

During the second quarter of 2023, the Company made a decision to streamline its operations by terminating clinic services and suspending non-lead R&D projects. This measure is aimed at optimizing the allocation of our resources and focusing our efforts on advancing our lead projects, which hold the most promise for commercial success and beneficial impact. This decision aligns with our commitment to enhance shareholder value and effectively drive our core objectives forward in the competitive landscape.

The following table summarizes our results of operations for the years ended December 31, 2023, and 2022.

	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue		
Healthcare services income	$ 431,378	$ 1,295,889
Operating expenses		
Cost of healthcare services	(420,812)	(1,215,824)
Research and development expenses	(5,198,329)	(9,219,595)
General and administrative fees	(1,930,637)	(5,220,405)
Legal and professional fees	(2,538,161)	(2,888,140)
Other operating expenses	(1,067,690)	(261,038)
Total expenses	(11,155,629)	(18,805,002)
Other income, net		
Loss on investments in marketable securities, net	(9,266)	(134,134)
Unrealized gain from fair value change of the long-term investments, net	6,431,088	6,108,872
Impairment loss of long-term investment	(77,200)	(520,821)
Interest (expense) income, net	(121,145)	146,588
Government subsidies	123,015	335,499
Sundry income	36,784	48,007
Total other income, net	6,383,276	5,984,011
Net loss	(4,340,975)	(11,525,102)

Revenue

Healthcare services income was $431,378 and $1,295,889 for the years ended December 31, 2023, and 2022, which related to the service income derived from clinic. The decline in healthcare services income was attributed primarily to the decision to terminate clinic services in the second quarter of 2023. This was done to reallocate resources towards the development of the Company's leading projects.

Cost of healthcare services

Cost of healthcare services was $420,812 and $1,215,824 for the years ended December 31, 2023, and 2022, which related to the cost incurred by clinic. The decline in cost of healthcare services was aligned with the decline in revenue when compared to last period.

Research and development expenses

The following table sets forth a summary of our research and development expenses for the years ended December 31, 2023, and 2022. As a consequence of exclusive emphasis on its lead projects and suspension of non-lead projects, there was a notable decrease in the utilization of external consultants and full impairment of patents related to these non-lead projects. Moreover, the payroll expenses for research and development staff decreased as a result of the reversal of deferred cash bonus payables to employees and consultants, and reduction of employees during current period. The reversal was due to the Group's agreements with employees and consultants to discharge the Group's obligation to settle their outstanding deferred cash bonus payables from previous years in exchange of fully vested ordinary shares.

	Year Ended December 31, 2023	**Year Ended December 31, 2022**
Research and Development Expenses:		
Payroll expenses	$ 363,139	$ 1,305,363
Contracted research organizations services	1,387,534	1,709,927
Sponsored research	17,149	17,061
Amortization and depreciation	1,071,455	1,064,012
Consultation	1,207,188	4,423,963
Loss on disposal and impairments of an intangible asset	519,497	205,189
Other R&D expenses	632,367	494,080
Total Research and Development Expenses	$ 5,198,329	$ 9,219,595

General and administrative fees

The following table sets forth a summary of our general and administrative expenses for the years ended December 31, 2023, and 2022. The decrease in general and administrative fees was primary due to the reversal of deferred cash bonus payables to employees and reduction of employees during current period. The reversal was due to the Group's agreements with employees to discharge the Group's obligation to settle their outstanding deferred cash bonus payables from previous years in exchange of fully vested ordinary shares.

	Year Ended December 31, 2023	**Year Ended December 31, 2022**
General and Administrative Fees:		
Payroll expenses	$ 893,437	$ 3,793,367
Rent and rates	213,701	265,558
Travelling expenses	59,874	158,357
Amortization and depreciation	53,799	143,498
Insurance	474,746	546,675
Advertising and marketing expenses	48,982	98,082
Other expenses	186,098	214,868
Total General and Administrative Fees	$ 1,930,637	$ 5,220,405

Legal and professional fees

For the years ended December 31, 2023, and 2022, the legal and professional fees were $2,538,161 and $2,888,140, respectively. The decrease in legal and professional fees was mainly due to less consulting services engaged during 2023 as a consequence of exclusive emphasis on its lead projects and suspension of non-lead projects.

Other operating expenses

For the years ended December 31, 2023, and 2022, the other operating expenses was $1,067,690 and $261,038, respectively. The increase in other operating expenses was primarily due to impairment losses of long-lived assets during current period, such as right-of-use assets, which resulted from the decision to terminate clinic services in the second quarter of 2023, and allowance of credit losses for amount due from related parties, which results from the decision to suspend non-lead projects owned by the related party.

Other income, net

For the years ended December 31, 2023, and 2022, the other income, net was $6,383,276 and $5,984,011, respectively. The increase in other income, net was mainly due to the increase in unrealized gain from fair value change of the long-term investments, net.

Net loss attributable to Aptorum Group Limited

For the years ended December 31, 2023, and 2022, net loss attributable to Aptorum Group Limited (excluding net loss attributable to non-controlling interests) was $2,824,647 and $9,799,560, respectively.

B. Liquidity and capital resources

The Group reported a net loss of $4,157,737 and net operating cash outflow of $1,189,734 for the year ended December 31, 2024. In addition, the Group had an accumulated deficit of $72,429,528 as of December 31, 2024. On January 2, 2025, the Group entered into a certain securities purchase agreement with certain non-affiliated institutional investors pursuant to which the Group sold 1,535,000 Class A Ordinary Shares of the Group, par value $0.00001 per share at a per share price of $2.00 in a registered direct offering, for gross proceeds of $3,070,000. The Group's operating results for future periods are subject to numerous uncertainties and it is uncertain if the Group will be able to reduce or eliminate its net losses for the foreseeable future. If management is not able to generate significant revenues from its product candidates currently in development, the Group may not be able to achieve profitability. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. In connection with the Company's assessment of going concern considerations in accordance with Financial Accounting Standard Board's Accounting Standards Update ("ASU") 2014-15, "Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern," management has determined that these conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

If the Group is unable to generate sufficient funds to finance the working capital requirements of the Group within the normal operating cycle of a twelve-month period from the date of these consolidated financial statements are issued, the Group may have to consider supplementing its available sources of funds through the following sources:

- other available sources of financing from banks and other financial institutions or private lender; and
- equity financing.

The Company can make no assurances that required financings will be available for the amounts needed, or on terms commercially acceptable to the Company, if at all. If one or all of these events does not occur or subsequent capital raises are insufficient to bridge financial and liquidity shortfall, there would likely be a material adverse effect on the Company and would materially adversely affect its ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Group will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Condensed Summary of Cash Flows for the Years Ended December 31, 2024, and 2023

	Year Ended December 31, 2024	Year Ended December 31, 2023
Net cash used in operating activities	$ (1,189,734)	$ (7,724,364)
Net cash provided by investing activities	58,621	624,767
Net cash provided by financing activities	-	4,092,068
Net decrease in cash and cash equivalents	(1,131,113)	(3,007,529)

Operating activities

Net cash used in operating activities amounted to $1.2 million and $7.7 million for the years ended December 31, 2024, and 2023. The net cash used in operating activities declined due to the implementation of stringent budgetary control measures, as a result of the Company's exclusive emphasis on the previously anticipated Merger.

Investing activities

Net cash used in investing activities amounted to $0.1 million and $0.6 million for the years ended December 31, 2024, and 2023. The decrease in net cash provided by investing activities was due to the decrease in cash received from related parties for loan repayment by $0.6 million.

Financing activities

Net cash provided by financing activities amounted to $nil and $4.1 million for the year ended December 31, 2024, and 2023. The decrease in net cash inflow from financing activities is attributed to the absence of financing activities during the period, as the Company was solely focused on the previously anticipated Merger.

Condensed Summary of Cash Flows for the Years Ended December 31, 2023 and 2022

	Year Ended December 31, 2023	**Year Ended December 31, 2022**
Net cash used in operating activities	$ (7,724,364)	$ (12,318,965)
Net cash provided by investing activities	624,767	2,444,896
Net cash provided by financing activities	4,092,068	6,625,462
Net decrease in cash and cash equivalents and restricted cash	(3,007,529)	(3,248,607)

Operating activities

Net cash used in operating activities amounted to $7.7 million and $12.3 million for the years ended December 31, 2023, and 2022. The net cash used in operating activities declined due to the implementation of stringent budgetary control measures, as a result of the Company's exclusive emphasis on its lead projects.

Investing activities

Net cash provided by investing activities amounted to $0.6 million and $2.4 million for the years ended December 31, 2023 and 2022. The decrease in net cash provided by investing activities was due to the decrease in net cash repayment from loan to related parties by $2.1 million, which was partially mitigated by a $0.2 million decrease in capital expenditures.

Financing activities

Net cash provided by financing activities amounted to $4.1 million and $6.6 million for the year ended December 31, 2023 and 2022. The decrease in net cash inflow from financing activities was primarily a result of the repayment of a bank loan in the amount of $3.0 million and decrease in loan from bank of $3.0 million, partially mitigated by a $2.0 million increase in loan from a related party, and a $1.6 million increase in proceeds from issuance of Class A Ordinary Shares.

CAPITAL EXPENDITURES

Our capital expenditures were $nil, $3,000 and $0.2 million for the years ended December 31, 2024, 2023 and 2022, respectively. These capital expenditures were incurred primarily for investments in facilities, leasehold improvements, equipment and technology.

COMMITMENTS

The following table sets forth our contractual obligations as of December 31, 2024.

	Payment Due by Period			
	Total US$	**less than one year US$**	**One to three years US$**	**Three to five years US$**
Operating lease commitments	122,114	97,541	24,573	-
Debt obligations	3,360,000	3,360,000	-	-
Total	3,482,114	3,457,541	24,573	-

Operating lease commitments

We have an operating lease for laboratory as of December 31, 2024. Operating lease commitments reflect our obligation to make payments under these operating leases.

Debt obligations

Debt obligations reflects outstanding principal and accrued interest payable to Jurchen Investment Corporation, the largest shareholder of the Company, pursuant to a convertible note arrangement. This instrument features a conversion option at a price of $2.42 per share into the Company's Class A Ordinary Shares. It carries a two-year maturity from the date of issuance and bears an annual interest rate of 6%.

The Group can access up to a total $12 million under a line of credit offered by Aeneas Group Limited. The line of credit was originally mature on August 12, 2022. The Group and Aeneas Group Limited has mutually agreed to extend the line of credit arrangement further 3 years to August 12, 2025. The interest on the outstanding principal indebtedness is at the rate of 8% per annum. The Group may early repay, in whole or in part, the principal indebtedness and all interest accrued at any time prior to the maturity date without the prior written consent of the lender and without payment of any premium or penalty.

CONTINGENT PAYMENT OBLIGATIONS

As of December 31, 2024, the Group does not have any non-cancellable purchase commitments.

The Group has contingency payment obligations under each of the license agreements, such as milestone payments, royalties, research and development funding, if certain condition or milestone is met.

Milestone payments are due upon achievements of specific conditions, such as Investigational New Drugs ("IND") filing or U.S. Food and Drug Administration ("FDA") approval, first commercial sale of the licensed products, or other achievements. The aggregate amounts of the contingent milestone payments that the Group is required to pay up to different achievements of conditions and milestones under all license agreements in effect as of December 31, 2024, are below:

	Amount
Drug molecules: up to the conditions and milestones of	
Preclinical to IND filing	$ 30,000
From entering phase 1 to before first commercial sale	2,120,000
First commercial sale	1,600,000
Net sales amount more than certain threshold in a year	14,000,000
Subtotal	$ 17,750,000
Diagnostics technology: up to the conditions and milestones of	
Before FDA approval	$ 146,417
	$ 17,896,417

For the years ended December 31, 2024, 2023 and 2022, the Group incurred $61,123, $50,000 and $nil milestone payments under license agreements, respectively. For the years ended December 31, 2024, 2023 and 2022, the Group did not incur any royalties or research and development funding, respectively.

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

As of the date of this annual report, the Company has 2 exclusively licensed technologies in the area of infectious diseases, and diagnostics. In addition, the Company is actively developing 1 proprietary technology.

For the years ended December 31, 2024, 2023, and 2022, the Group incurred $2,195,161, $5,198,329, and $9,219,595, respectively, on research and development expenses.

D. Trend Information

Other than as disclosed elsewhere in this annual report, we are not aware of any material recent trends in production, sales and inventory, the state of the order book and costs and selling prices since our last fiscal year. We are also unaware of any known trends, uncertainties, demands, commitments or events for the year ended December 31, 2024, that are reasonably likely to have a material adverse effect on our revenues, net income, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial conditions.

E. Critical Accounting Estimates

In preparing the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. However, uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amount of the assets or liabilities in the future.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. The management determines there are no critical accounting estimates.

Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

Below is a list of our directors, senior management and any employees upon whose work we are dependent as of the date of this annual report, and a brief account of the business experience of each of them. The business address for the directors and officers of Aptorum Group Limited is 17 Hanover Square, London, W1S 1BN, United Kingdom.

In August 2024, Mr. Martin Siu resigned from his position as Head of Finance of Aptorum Group due to personal reason. Mr. K.K. Wong ("Mr. Wong") has replaced Mr. Siu as the Company's Head of Finance since August 2024.

In October 2024, Dr. Mirko Scherer and Mr. Charles Bathurst resigned from their position as directors of Aptorum Group Limited's Board of Directors, due to personal reasons. As a result of the resignations, Mr. Douglas Arner will assume Mr. Bathurst's role as Chair of our Audit Committee.

Name	Age	Position
Executive Officers		
Ian Huen	45	Founder, Chief Executive Officer and Executive Director
K.K. Wong	69	Head of Finance
Non-Management Directors		
Justin Wu	55	Independent Non-Executive Director and Chair of Compensation Committee
Douglas Arner	55	Independent Non-Executive Director and Chair of Nominating and Corporate Governance Committee and Audit Committee

Executive Officers

MR. IAN HUEN, Founder, Chief Executive Officer and Executive Director

Mr. Ian Huen is the Founder, Chief Executive Officer and an Executive Director of Aptorum Group Limited. Mr. Huen previous served as Non-Executive Director of Aptorum Group from June 2022 to November 2023, and as Chief Executive Officer and Executive Director of Aptorum Group Limited from October 2017 to May 2022. He has extensive experience in global asset management and previously covered the U.S. healthcare sector as an equity research analyst at Janus Henderson Group plc (formerly known as Janus Capital). Mr. Huen was the financial advisor in the sale of Seng Heng Bank Limited (Macau) to Industrial and Commercial Bank of China in 2007 and was appointed as the vice president of the Board of General Meeting in Industrial and Commercial Bank of China (Macau) Capital Limited in March 2007 for a term of 12 years until March 2019.

As a trustee board member of the Dr. Stanley Ho Medical Development Foundation, Mr. Huen facilitates advisory, development funding, access to research resources across Asia and continues to establish relationships with leading academic institutions to propel innovations in healthcare.

Mr. Huen graduated from Princeton University with an A.B. degree in Economics in June 2001, earned a MA in Comparative and Public History from CUHK in June 2016. Mr. Huen is also a Chartered Financial Analyst ("CFA").

MR. K.K WONG, Head of Finance

Mr. K.K. Wong is the Head of Finance of Aptorum Group Limited since August 2024. Mr. Wong has over twenty-eight years of banking experience specializing in credit, marketing, and management role in the Greater China region. Past roles that Mr. Wong has served includes being the General Manager at the Industrial & Commercial Bank of China (Macau) for 5 years, Deputy General Manager at Credit Agricole CIB Bank in Hong Kong for 5 years, and various senior roles in Hong Kong at BNP Paribas for over 16 years. Mr. Wong holds a degree in Master of Business Administration from Bangor University, United Kingdom, in cooperation with Alliance Manchester Business School, United Kingdom. He is an associate of LIBF, CGI and HKCGI and has also been awarded the CGP qualification. Additionally, Mr. Wong is a member of Institute of Certified Management Account (ICMA, Australia), Fellow of Institute of Financial accountants (FFA), Fellow of Institute of Public accountant, Australia (FIPA) and an International Affiliate Member of the Hong Kong Institute of Certified Public Accountants (HKICPA).

Non-Executive Directors

PROFESSOR JUSTIN WU

Professor Justin Wu is an Independent Non-Executive Director of Aptorum Group Limited. He also has been serving as the Chief Operating Officer of CUHK Medical Centre since August 2018. He served as the Associate Dean (Development) of the Faculty of Medicine at CUHK from July 2014 to June 2018 and the Associate Dean (Clinical) of the Faculty of Medicine at CUHK from December 2012 to July 2014, and has been serving a Professor in the Department of Medicine and Therapeutics since 2009, also the Director of the S. H. Ho Center for Digestive Health, a research center specializing in functional gastrointestinal diseases, reflux and motility disorders, and digestive endoscopy. Active in research publications and assessments, Professor Wu served as the International Associate Editor of American Journal of Gastroenterology ("AJG"), and Managing Editor of Journal of Gastroenterology and Hepatology ("JGH"). He is also the Secretary General of the Asian Neurogastroenterology and Motility Association ("ANMA"), and Secretary General of the Asia Pacific Association of Gastroenterology ("APAGE").

Professor Wu has won a number of awards including the Emerging Leader in Gastroenterology Award by the JGH Foundation, and the Vice Chancellor's Exemplary Teaching Award at CUHK. Aside from his expertise in gastroenterology, Professor Wu has an extensive interest in the development of Integrative Medicine in Hong Kong. He is the Founding Director of the Hong Kong Institute of Integrative Medicine, working closely with the School of Chinese Medicine to develop an integrative model at an international level. The institute aims at maximizing the strength of Western and Chinese medicine to provide a safe and effective integrative treatment to patients.

Professor Wu served as a consultant and an advisory board member for Takeda Pharmaceutical, AstraZeneca, Menarini, Reckitt Benckiser and Abbott Laboratory. He earned his Bachelor of Medicine and Bachelor of Surgery Degree (1993), and his Doctor of Medicine Degree (2000) from CUHK. Additionally, he attained Fellowships of the Royal College of Physicians of Edinburgh and London in 2007 and 2012 respectively, Fellowship of the Hong Kong College of Physicians in 2002, Fellowship of the Hong Kong Academy of Medicine in 2002, and has been an American Gastroenterological Association Fellow since 2012.

PROFESSOR DOUGLAS ARNER

Professor Douglas W. Arner is an Independent Non-Executive Director of Aptorum Group Limited. Douglas is the Kerry Holdings Professor in Law and Director and co-founder of the Asian Institute of International Financial Law at the University of Hong Kong, as well as Faculty Director and co-founder of the LLM in Compliance and Regulation, LLM in Corporate and Financial Law, and Law, Innovation, Technology and Entrepreneurship (LITE) Programmes. He served as Head of the HKU Department of Law from 2011 to 2014 and as Co-Director of the Duke University-HKU Asia-America Institute in Transnational Law from 2005 to 2016. Douglas has published eighteen books and more than 200 articles, chapters and reports on international financial law and regulation, most recently Reconceptualising Global Finance and its Regulation (Cambridge 2016) (with Ross Buckley and Emilios Avgouleas) and The RegTech Book (Wiley 2019 (Janos Barberis and Ross Buckley). His recent papers are available on SSRN at https://papers.ssrn.com/sol3/cf_dev/AbsByAuth.cfm?per_id=524849, where he is among the top 75 authors in the world by total downloads. Professor Arner led the development of Introduction to FinTech – launched with edX in May 2018 and now with over 80,000 learners spanning the world – and the foundation of the edx-HKU Online Professional Certificate in FinTech. He is a Senior Visiting Fellow of Melbourne Law School, University of Melbourne, a non-executive director of NASDAQ and Euronext listed Aptorum Group and an Advisory Board Member of the Centre for Finance, Technology and Entrepreneurship (CFTE). Professor Arner was an inaugural member of the Hong Kong Financial Services Development Council (2013-2019) and has served as a consultant with, among others, the World Bank, Asian Development Bank, APEC, Alliance for Financial Inclusion, and European Bank for Reconstruction and Development. He has lectured, co-organized conferences and seminars and been involved with financial sector reform projects around the world. Professor Arner has been a visiting professor or fellow at Duke, Harvard, the Hong Kong Institute for Monetary Research, IDC Herzliya, McGill, Melbourne, National University of Singapore, University of New South Wales, Shanghai University of Finance and Economics, and Zurich, among others. Professor Arner is the Senior Regulatory & Strategic Advisor of Aeneas Group, a multi-disciplinary financial services institution with technology-driven growth initiatives.

He holds a BA from Drury College (where he studied literature, economics and political science) in 1992, a JD (cum laude) from Southern Methodist University in 1995, an LLM (with distinction) in banking and finance law from the University of London (Queen Mary College) in 1996, and a PhD from the University of London in 2005.

B. Compensation of Executive Directors and Executive Officers

The following table sets forth all cash compensation paid by us, as well as certain other compensation paid or accrued, in fiscal 2023 to each of the following named executive officers. The total amount was $0.1 million in 2024. This amount does not include business travel, relocation, professional and business association dues, and expenses reimbursed to such persons, and other benefits commonly reimbursed or paid by companies in our industry. (See “Item 6. Directors, Senior Management and Employees – E. Share Ownership”)

In accordance with mutual agreements reached with the board of directors, Mr. Ian Huen has agreed to forgo their monthly remuneration effective July 1, 2023 until further notice. Before the suspension of remuneration, Mr. Ian Huen had a monthly remuneration of $27,333.

In August 2024, Mr. Martin Siu resigned from his position as Head of Finance of Aptorum Group due to personal reason. Mr. K.K. Wong (“Mr. Wong”) has replaced Mr. Siu as the Company’s Head of Finance since August 2024. As of this time, Mr. Wong does not receive any remuneration, and it is subject to change based on subsequent discussions between the Company and Mr. Wong.

In October 2024, Dr. Mirko Scherer and Mr. Charles Bathurst resigned from their position as directors of Aptorum Group Limited’s Board of Directors, due to personal reasons. As a result of the resignations, Mr. Douglas Arner will assume Mr. Bathurst’s role as Chair of our Audit Committee.

The base salary of all directors and senior officer remains unchanged in 2024.

Name and Principal Position	Fiscal Year	Salary ($) [1]	Bonus ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Ian Huen [2] (CEO)	**2024**	-	-	-	-	-	-	-
K.K. Wong [3] (Head of Finance)	**2024**	-	-	-	-	-	-	-
Martin Siu [4] (former Head of Finance)	**2024**	62,820	-	-	-	-	-	62,820

(1) The Appointment Letters provide salaries in HKD; for purposes of this table, we used a conversion ratio of HKD7.80 to USD1.00 to determine the salary in USD.

(2) Mr. Huen is the founder of Aptorum Group, and was re-appointed as Chief Executive Officer and Executive Officer in November 2023. He was previously appointed as non-executive director from June 2022 to November 2023, and appointed as the Chief Executive Officer and Executive Director from October 2017 to May 2022.

(3) Mr. Wong was appointed as Head of Finance of Aptorum Group from August 2024.

(4) Mr. Siu served as the Head of Finance from July 2022 to August 2024.

Compensation of Non-executive Directors

The following table sets forth information for the fiscal year ended December 31, 2024, regarding the compensation of our non-executive directors who at December 31, 2024, were not also named executive officers.

In accordance with mutual agreements reached with the board of directors, Mr. Charles Bathurst, Dr. Mirko Scherer, Professor Justin Wu and Professor Douglas Arner have consented to suspend their monthly remuneration from September 1, 2023 until further notice.

In October 2024, Dr. Mirko Scherer and Mr. Charles Bathurst resigned from their position as directors of Aptorum Group Limited's Board of Directors, due to personal reasons.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Justin Wu [(1)]	-	-	-	-	-	-	-
Douglas Arner [(2)]	-	-	-	-	-	-	-
Charles Bathurst [(3)]	**15,835**[(4)]	-	-	-	-	-	**15,835**
Mirko Scherer [(5)]	**10,558**	-	-	-	-	-	**10,558**

(1) Professor Wu was appointed as one of our directors as of October 2017 and is entitled to receive $31,673 annually for his combined services as a director and a committee member effective from January 1, 2022.

(2) Professor Arner's appointment as one of our directors became effective as of April 1, 2018, and is entitled to receive $31,673 annually for his combined services as a director and a committee member effective from January 1, 2022.

(3) Mr. Bathurst was appointed as one of our directors as of October 2017 and is entitled to receive $50,676 annually for his combined services as a director and a committee member effective from January 1, 2022. In October 2024, Mr. Bathurst resigned from his position as director of Aptorum Group Limited's Board of Directors and received GBP12,668 as his final compensation.

(4) Mr. Bathurst's appointment Letter provides his salary in GBP. For purposes of this table, we used a conversion ratio of GBP0.8 to USD1.00 to determine his salary in USD; however, the ultimate amount paid is based on the actual rate as of the relevant pay day at the end of each month.

(5) Dr. Scherer was appointed as one of our directors as of October 2017 and is entitled to receive $31,673 annually for his services as a director effective from January 1, 2022. In October 2024, Dr. Scherer resigned from his position as director of Aptorum Group Limited's Board of Directors and received $10,558 as his final compensation.

2017 Share Option Plan

On October 13, 2017, we adopted the 2017 Share Option Plan (the "Option Plan") and on November 5, 2021, we amended the Option Plan. Under the Option Plan, up to an aggregate of 550,000 Class A Ordinary Shares (subject to subsequent adjustments described more fully below) may be issued pursuant to awards under the Option Plan. Subsequent adjustments include that on each January 1, starting with January 1, 2020, an additional number of shares equal to the lesser of (A) 2% of the outstanding number of Class A Ordinary Shares (on a fully diluted basis) on the immediate preceding December 31, and (B) such lower number of Class A Ordinary Shares as may be determined by the board of directors, subject in all cases to adjustments as provided in Section 10 of the Option Plan. Awards will be made pursuant to agreements and may be subject to vesting and other restrictions as determined by the board of directors.

We adopted the Option Plan to provide additional incentives to selected directors, officers, employees and consultants, and enable our Company to obtain and retain the services of these individuals. The Option Plan will enable us to grant options, restricted shares or other awards to our directors, employees and consultants. Awards will be made pursuant to agreements and may be subject to vesting and other restrictions as determined by the board of directors.

21,853 options were granted on March 15, 2019 to directors, employees, external consultants and advisors of the Group. One-half of each option grant vests on January 1, 2020 and expires on December 31, 2030, and the other half vests on January 1, 2021 and expires on December 31, 2031. The exercise price is $129.1 per share, which was based on the closing price of the shares traded on the NASDAQ stock exchange on the trading day preceding the grant date.

53,694 options were granted on March 16, 2020 to directors, employees, external consultants and advisors of the Group. One-half of each option grant vests on January 1, 2021 and expires on December 31, 2031 and the other half vests on January 1, 2022, and expires on December 31, 2032. The exercise price is $29.9 per share, which was based on the average closing price of the shares traded on the NASDAQ stock exchange for the five trading days immediately preceding the grant date.

14,896 options were granted on June 1, 2020 to directors and employees of the Group. Nearly one-half of each option grant vests on December 1, 2020 and expires on November 30, 2030 and the remaining vests on January 1, 2021 and expires on December 31, 2031. The exercise price is US$31.1 per share, which was based on the average closing price of the shares traded on the NASDAQ stock exchange for the five trading days immediately preceding the grant date.

2,748 options were granted on August 10, 2020 to Dr. Weiss, which will be vested on August 10, 2021 and expires on August 9, 2032. The exercise price is $36.4 per share, which was based on the average closing price of the shares traded on the NASDAQ stock exchange for the five trading days immediately preceding the grant date.

75,235 options were granted on March 11, 2021 to directors, employees, external consultants and advisors of the Group with an exercise price of $27.6 per share, which was based on the average closing price of the shares traded on the NASDAQ stock exchange for the five trading days immediately preceding the grant date. 36,796 options vest on January 1, 2022, and expire on December 31, 2032; 36,808 options vest on January 1, 2023 and expire on December 31, 2033; 906 options vest on June 8, 2021 and expire on June 7, 2032; and 725 options vest on July 14, 2021 and expire on July 13, 2032.

153,146 options were granted on March 8, 2022, to directors, employees, external consultants and advisors of the Group with an exercise price of $13.4 per share, which was based on the average closing price of the shares traded on the NASDAQ stock exchange for the five trading days immediately preceding the grant date. 74,881 options vest on January 1, 2023, and expire on December 31, 2033; 74,906 options vest on January 1, 2024, and expire on December 31, 2034; 1,866 options vest on June 8, 2022, and expire on June 7, 2033; and 1,493 options vest on July 14, 2022, and expire on July 13, 2033.

On March 31, 2023, we entered into exchange agreements and cancelled 177,667 existing vested and unvested share options held by related parties option holders and cancelled our obligations for deferred cash bonus payables of $3.1 million by granting of 403,820 share options ("New Options") with 6 months vesting period. The New Options' exercise price was $2.68 per share, which was based on the last closing price of the shares traded on the NASDAQ stock exchange on the grant date. All options fully vested on October 1, 2023, and expires on September 30, 2033. On March 31, 2023, we entered into supplemental agreements with the same related parties option holders to provide additional cash compensation to cover the exercise price of the New Options. On March 31, 2023, we entered into exchange agreements and cancelled 70,428 existing vested and unvested share options held by non-related parties option holders and cancelled our obligations for deferred cash bonus payables of $1.6 million by issuance of 70,430 fully vested Class A Ordinary Shares. We accounted for this exchange for both related parties and non-related parties share option holders as a modification to share based compensation which required the remeasurement of existing share options value at the time of the modification. The total incremental cost as a result of the modification was $0.7 million.

In line with Nasdaq requirements, we have established a clawback policy which, subject to limited exceptions, requires that any incentive compensation (including both cash and equity compensation) paid to any current or former executive officer on or after October 2, 2023, is subject to recoupment if (i) the incentive compensation was calculated based on financial statements that were required to be restated due to material noncompliance with financial reporting requirements, without regard to any fault or misconduct; and (ii) that noncompliance resulted in overpayment of the incentive compensation within the three fiscal years preceding the date the restatement. A copy of our clawback policy has been filed as Exhibit 97.1 to this annual report on Form 20-F.

C. Board Practices

Board of Directors

Our Board of Directors currently consists of seven members, all of whom were elected pursuant to our current Memorandum and Articles. Our nominating and governance committee and board of directors will consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity and is not limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our shareholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy.

Committees of the Board of Directors

Our Board of Directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a separate charter adopted by our Board of Directors. The composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the NASDAQ Capital Market and SEC rules and regulations. Our Board of Directors may establish other committees from time to time.

Audit Committee

Douglas Arner and Justin Wu currently serve on the audit committee, which is chaired by Douglas Arner. Our Board of Directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable rules of the NASDAQ Capital Market. The audit committee's responsibilities include:

- selecting and appointing our independent registered public accounting firm, and approving the audit and permitted non-audit services to be provided by our independent registered public accounting firm;
- evaluating the performance and independence of our independent registered public accounting firm;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements or accounting matters;
- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures;
- establishing procedures for the receipt, retention and treatment of accounting-related complaints and concerns;
- reviewing and discussing with the independent registered public accounting firm the results of our year-end audit, and recommending to our Board of Directors, based upon such review and discussions, whether our financial statements shall be included in our annual report on Form 20-F;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing the type and presentation of information to be included in our earnings press releases, as well as financial information and earnings guidance provided by us to analysts and rating agencies.

Audit Committee Financial Expert

We have one financial expert as of the date of this report. Our Board of Directors has determined that Douglas Arner, Chair of our audit committee, qualifies as an "audit committee financial expert" as defined in the SEC rules and satisfies the financial sophistication requirements of The NASDAQ Capital Market.

Compensation Committee

Douglas Arner and Justin Wu currently serve on the compensation committee, which is chaired by Justin Wu. Our Board of Directors has determined that each member of the compensation committee is "independent" as that term is defined in the applicable rules of the NASDAQ Capital Market. The compensation committee's responsibilities include:

- reviewing the goals and objectives of our executive compensation plans, as well as our executive compensation plans in light of such goals and objectives;
- evaluating the performance of our executive officers in light of the goals and objectives of our executive compensation plans and recommending to our Board of Directors with respect to the compensation of our executive officers;
- reviewing the goals and objectives of our general compensation plans and other employee benefit plans as well as our general compensation plans and other employee benefit plans in light of such goals and objectives;
- retaining and approving the compensation of any compensation advisors;
- reviewing all equity-compensation plans to be submitted for shareholder approval under the NASDAQ listing rules, and reviewing and approving all equity-compensation plans that are exempt from such shareholder approval requirement;
- evaluating the appropriate level of compensation for board and board committee service by non-employee directors; and
- reviewing and approving description of executive compensation included in our annual report on Form 20-F.

Nominating and Corporate Governance Committee

Douglas Arner and Justin Wu currently serve on the nominating and corporate governance committee, which is chaired by Professor Arner. Our Board of Directors has determined that each member of the nominating and corporate governance committee is "independent" as that term is defined in the applicable rules of the NASDAQ Capital Market. The nominating and corporate governance committee's responsibilities include:

- assisting our Board of Directors in identifying prospective director nominees and recommending nominees for election by the shareholders or appointment by our Board of Directors;
- advising the board of directors periodically with respect to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to our Board of Directors on all matters of corporate governance and on any corrective action to be taken;
- overseeing the evaluation of our Board of Directors; and
- recommending members for each board committee of our Board of Directors.

*Scientific Advisory Board*s

We restructured the Scientific Assessment Committee into a newly formed Scientific Advisory Board. The Scientific Advisory Board shall help the Company sharpen its focus on innovation and technological advancements and address critical scientific challenges in our research and development; it will provide overall advise on the scientific development of the company. As of the date of this annual report, we have 29 members on this board.

In light of the Company's focus on developing treatment for infectious diseases, we have established a second scientific advisory board, i.e., the Infectious Diseases Scientific Advisory Board in April 2020. As of the date hereof, the Infectious Diseases Scientific Advisory Board has 4 members.

Family Relationships

There is no family relationship among any of our directors or executive officers.

Duties of Directors

Under Cayman Islands law, our directors have a duty to act honestly, in good faith and bona fide with a view to our best interests. Our directors also have a duty to exercise the care, diligence and skills that a reasonably diligent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our Memorandum and Articles. We have the right to seek damages if a duty owed by our directors is breached.

The functions and powers of our Board of Directors include, among others:

- appointing officers and determining the term of office of the officers;
- authorizing the payment of donations to religious, charitable, public or other bodies, clubs, funds or associations as deemed advisable;
- exercising the borrowing powers of the company and mortgaging the property of the company;
- executing checks, promissory notes and other negotiable instruments on behalf of the company; and
- maintaining or registering a register of mortgages, charges or other encumbrances of the company.

Terms of Directors and Officers

There is no Cayman Islands law requirement that a director must hold office for a certain term and stand for re-election unless the resolutions appointing the director impose a term on the appointment. The Memorandum and Articles provide that we have a staggered board of directors consisting of three classes of directors, with directors serving staggered three-year terms. Our Board of Directors is divided into three classes of directors. At each annual general meeting of shareholders, one class of directors will be elected for a three-year term to succeed the class whose terms are then expiring, to serve from the time of election and qualification until the third annual meeting following their election or until their earlier death, resignation or removal, starting with the Annual General Meeting of Shareholders held in December 2023. The Company's Board has initially designated the three classes to contain the directors set forth below. Shareholders will only elect the Class II directors at the Company's next Annual General Meeting; the Class III and I directors shall not be required to stand for re-election until the years specified below.

Name & Class	Positions	Expiration of Director Term/Re-Election Year
Class III		
Ian Huen	Chief Executive Officer & Executive Director	2027
Class II		
Not applicable		
Class I		
Justin Wu	Independent Non-Executive Director	2026
Douglas Arner	Independent Non-Executive Director	2026

We do not have any age limit requirements relating to our director's term of office.

Our Memorandum and Articles also provide that our directors may be removed by the directors or ordinary resolution of the shareholders, and that any vacancy on our Board of Directors, including a vacancy resulting from an enlargement of our Board of Directors (which shall not exceed any maximum number stated therein), may be filled by ordinary resolution or by vote of a majority of our directors then in office.

Employment Agreements

We have entered into agreements with our executive officers. Each of our executive officers is employed for a specified time period, which will be renewed upon both parties' agreement. We may terminate the employment for cause, at any time, without notice or remuneration, for certain acts of the executive officer, including but not limited to the commitments of any serious or persistent breach or non-observance of the terms and conditions of the employment, conviction of a criminal offense, willful disobedience of a lawful and reasonable order, fraud or dishonesty, receipt of bribery, or severe neglect of his or her duties.

Each executive officer has agreed to hold, both during and after the employment agreement expires, in strict confidence and not to use or disclose to any person, corporation or other entity without written consent, any confidential information. Each executive officer has also agreed to assign to our group all his or her all inventions, improvements, designs, original works of authorship, formulas, processes, compositions of matter, computer software programs, databases, mask works, concepts, and trade secrets.

D. Employees

As of the date of this annual report, we have 1 full-time employees. Of these, 1 full-time are engaged in general and administrative functions. As of the date of this annual report, all of our employees are located in Asia. In addition, we have engaged and may continue to engage 8 independent contracted consultants and advisors to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment related work stoppages, and we consider our relations with our employees to be good.

E. Share Ownership

The following table sets forth information with respect to the beneficial ownership, within the meaning of Rule 13d-3 under the Exchange Act, of our Ordinary Shares as of the date of this annual report.

- each of our directors and executive officers who beneficially own our Ordinary Shares; and
- each person known to us to own beneficially more than 5.0% of our Ordinary Shares.

Beneficial ownership includes voting or investment power with respect to the securities. Except as indicated below, 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 shown as beneficially owned by them. Percentage of beneficial ownership of each listed person is based on 5,346,823 Class A Ordinary Shares and 1,796,934 Class B Ordinary Shares outstanding as of the date of this annual report.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of 5% or more of our Ordinary Shares. Beneficial ownership is determined in accordance with the rules of the SEC and generally requires that such person have voting or investment power with respect to securities. In computing the number of Ordinary Shares beneficially owned by a person listed below and the percentage ownership of such person, Ordinary Shares underlying options, warrants or convertible securities held by each such person that are exercisable or convertible within 60 days of the date of this annual report are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. Except as otherwise indicated in the footnotes to this table, or as required by applicable community property laws, all persons listed have sole voting and investment power for all Ordinary Shares shown as beneficially owned by them. As of the date of the annual report, we have 2 shareholders of record holding beneficial ownership of 5% or more, none of which are located in the United States.

Unless otherwise indicated, the business address of each of the individuals is 17 Hanover Square, London, W1S 1BN, United Kingdom.

Name and Address of Beneficial Owner	Class A Ordinary Shares Beneficially Owned	Class B Ordinary Shares Beneficially Owned	Percentage of Total Class A and Class B Ordinary Shares[1]	Percentage of Total Voting Power[2]
Ian Huen[3]	1,900,244	1,606,147	48.71%	87.17%
K.K. Wong	-	-	-	-
Justin Wu	*	-	*	*
Douglas Arner	*	-	*	*
All directors and executive officers as a group (4 persons)	1,942,140	1,606,147	49.29%	87.19%
5% Beneficial Owner				
Jurchen Investment Corporation[3]	1,762,585	1,606,147	39.46%	87.10%
CGY Investments Limited[4]	533,575	-	7.47%	0.29%
L1 Capital Global Opportunities Master Fund, Ltd.	383,750	-	5.37%	0.21%

* Less than 1% of total outstanding Ordinary Shares on an as converted basis.

(1) For each person and group included in this column, percentage ownership is calculated by dividing the number of Class A Ordinary Shares and Class B Ordinary Shares beneficially owned by such person or group, including shares that such person or group has the right to acquire within 60 days after the date of this annual report, by the sum of Class A Ordinary Shares and Class B Ordinary Shares, and the number of Class A Ordinary Shares that such person or group has the right to acquire beneficial ownership within 60 days after the date of this annual report. Following the IPO, each Class B Ordinary Share can be converted at any time on a one-for-one basis into Class A Ordinary Shares at the discretion of the holder.

(2) For each person and group included in this column, percentage of total voting power represents voting power based on both Class A Ordinary Shares and Class B Ordinary Shares beneficially owned by such person or group with respect to all of our outstanding Class A Ordinary Shares and Class B Ordinary Shares as one single class. Holders of Class A Ordinary Shares are entitled to one vote per share and holders of Class B Ordinary Shares are entitled to one hundred votes per share on all matters subject to a shareholders' vote.

(3) Includes 370,308 Class A Ordinary Shares owned by Jurchen, warrants held by Jurchen to purchase 54,054 Class A Ordinary Shares, convertible notes held by Jurchen to convert 1,338,223 Class A Ordinary Shares, 137,659 Class A Ordinary Shares owned by Mr. Huen, and 1,606,147 Class B Ordinary Shares owned by Jurchen. Jurchen Investment Corporation, is a company wholly owned by Mr. Huen. Mr. Huen maintains sole voting control over the shares held by Jurchen, the principal office address of which is at 17th Floor, Guangdong Investment Tower, 148 Connaught Road Central, Hong Kong.

(4) CGY Investments Limited is 50% held by Seng Fun Yee, 25% held by Mandy Lui and 25% held by Adrian Lui (all of whom are related to our former CEO, Mr. Darren Lui). Mr. Lui controls and/or has substantial influence on the disposition and voting rights of the shares held by his spouse, but no such control over the shares held by his sister or brother. Includes 533,575 Class A Ordinary Shares held by CGY Investments Limited.

F. Disclosure of a registrant's action to recover erroneously awarded compensation.

None.

Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

Please refer to "Item 6. Directors, Senior Management and Employees—E. Share Ownership."

B. Related Party Transactions

Lines of Credit

On August 13, 2019 (the "Effective Date"), Aptorum Therapeutics Limited ("ATL"), one of our wholly owned subsidiaries, entered into two separate Promissory Notes and Line of Credit Agreements (the "Agreements") with Aeneas Group Limited and Jurchen Investment Corporation ("Jurchen"). The Aeneas Group Limited Agreement and Jurchen Agreement provide ATL with a line of credit up to twelve million dollars ($12,000,000) and three million dollars ($3,000,000), respectively (collectively, the "Line of Credit"), representing the maximum aggregate amount of the advances of funds from the Line of Credit that may be outstanding at any time under the Line of Credit (the "Principal Indebtedness"). ATL may draw down from the Line of Credit at any time through the day immediately preceding the third anniversary of the Effective Date (the "Maturity Date"). As of the date of this annual report, the Jurchen Agreement is matured, and the maturity of Aeneas Group Limited Agreement is extended for additional three years and will be matured on August 12, 2025. Interest is payable on the outstanding Principal Indebtedness at the rate of eight percent (8%) per annum, payable semi-annually in arrears on February 12 and August 12 in each year. ATL may pre-pay in whole or in part, the Principal Indebtedness of the Line of Credit, and all interest accrued at any time prior to the Maturity Date, without penalty. Under the Agreements, in addition to certain standard covenants, we are also not permitted, without the prior written consent of Aeneas Group and Jurchen to (i) liquidate, dissolve or wind-up our business and affairs; (ii) effect any merger or consolidation transaction; (iii) sell, lease, transfer, license or otherwise dispose, in a single transaction or series of related transactions, all or substantially all of our assets; or (iv) consent to any of the foregoing. The Agreements are subject to standard events of default, which if not cured within the agreed upon cure period, permits Aeneas Group Limited or Jurchen, as applicable, to declare the outstanding Principal Indebtedness immediately due and payable, to exercise any other remedy provided for in the Agreements or any other right available to Aeneas Group Limited or Jurchen as provided at law or in equity. Jurchen and Aeanas Group Limited also maintain the right to set-off during the term of the Agreements. As of the date of this annual report, the Company has not drawn down from the Line of Credit.

On January 13, 2022, the Group entered a line of credit facility with Libra to provide up to a total $1 million in line of credit debt financing for its daily operation The line of credit is originally matured on January 12, 2023, and is extended for additional 3 years. The interest on the outstanding principal indebtedness is at the rate of 10% per annum. As of the date of this annual report, $0.5 million is outstanding from Libra Sciences Limited. For the year ended December 31, 2023 and December 31, 2024, the Group has assessed that the amounts due from Libra Science Limited and its subsidiary are potentially unrecoverable, an allowance for credit loss amounting to $0.5 million and $1,184 has been recognized for the year ended December 31, 2023 and December 31, 2024.

Sales and Purchases of Securities

Private Placement Offering

Sale of Class A Ordinary Shares

On May 26, 2021, the Company entered into a private placement shares purchase agreement with Jurchen, issuing 138,793 Class A Ordinary Shares, par value $10 each, at $28.82 per share, representing a 10% premium to the last closing price of the Company's Class A Ordinary Shares on the NASDAQ stock exchange on that date. The Company received aggregate gross proceeds of $4,000,000 from the purchase of these shares.

Sales of convertible notes

On December 9, 2022, the Group entered into a securities purchase agreement with Aenco Technologies Limited ("Aenco"). Pursuant to the securities purchase agreement, Aenco is purchasing a convertible note in the original principal amount of $3,000,000 (the "Dec 2022 Note"). The Dec 2022 Note is unsecured, convertible into the Company's restricted Class A Ordinary Shares at Aencco's option. The Dec 2022 Notes have a maturity date of 12 months subject to the Aenco's extension, a bullet interest rate of 7% per annum, and a conversion price of $12.00 per Class A Ordinary share. The Company shall have an obligation to repay the principal amount and interest of the Dec 2022 Note on the maturity date in cash or in unregistered Class A Ordinary Shares or a combination of such at the Company's discretion. In April 2023, Aenco transferred the whole Dec 2022 Note to two external investors, and the two external investors fully converted the Dec 2022 Note into 250,000 Class A Ordinary Shares.

On June 28, 2023, the Group entered into a securities purchase agreement with 4 investors. Pursuant to the securities purchase agreement, the investors are purchasing a convertible note in the original principal amount of $3,000,000 (the "June 2023 Note"). The whole proceeds from the June 2023 Note was used to settle a related party loan. The June 2023 Note is unsecured, convertible into the Company's restricted Class A Ordinary Shares at the Note holder option. The June 2023 Notes have a maturity date of 12 months subject to the investors extension, a bullet interest rate of 7% per annum, and a conversion price of $3.00 per Class A Ordinary share. The Company shall have an obligation to repay the principal amount and interest of the June 2023 Note on the maturity date in cash or in unregistered Class A Ordinary Shares or a combination of such at the Company's discretion. Immediately following the issuance of June 2023 Note, the June 2023 Note was fully converted into 1,000,000 Class A Ordinary Shares.

On September 11, 2023, the Group entered into a securities purchase agreement with Jurchen Investment Corporation, the largest shareholder of the Company, pursuant to which the Group sold a secured convertible note in the aggregate principal amount of $3,000,000 (the "Sep 2023 Notes"). The Sep 2023 Notes are convertible into the Company's Class A Ordinary Shares and have a maturity date that is 24 months from the issuance date, although upon such date the investor has the right to extend the term of the Sep 2023 Note for twelve (12) months or more or such term subject to mutual consent. The Sep 2023 Notes have an interest rate of 6% per annum and a conversion price of $2.42 per share. The Company has the right to repay the principal amount of the Sep 2023 Notes, but in the case of such prepayment it must be paid in cash, unless otherwise agreed by both parties. The Sep 2023 Note is secured by a first priority lien and security interest on certain shares that the Group owns ("Collateral"). Upon the Group's disposal of all or a portion of the Collateral, the investor has the right, to request that the Group prepay the then-remaining outstanding balance of the Sep 2023 Note, in part or in full and the Group can make that payment in cash or in shares.

On January 2, 2025, the Company entered into a certain securities purchase agreement (the "Securities Purchase Agreement") with certain non-affiliated institutional investors (the "Purchasers") pursuant to which the Company sold 1,535,000 Class A ordinary shares of the Company (the "Shares"), par value $0.00001 per share (the "Ordinary Shares") at a per share price of $2.00 in a registered direct offering, for gross proceeds of $3,070,000 (the "Offering"). The Company agreed in the Securities Purchase Agreement that, subject to certain exceptions, for thirty (30) calendar days following the closing of the Offering (the "Standstill Period"), it would not (i) issue, or enter into any agreement to issue or announce the issuance or proposed issuance of any Ordinary Shares, or any securities of the Company or its subsidiaries which would entitle the holder thereof to acquire at any time Ordinary Shares (the "Ordinary Share Equivalents"), or (ii) file any registration statement or amendment or supplement thereto, other than the Prospectus Supplement contemplated in the Securities Purchase Agreement and the filing of a registration statement on Form S-8 in connection with any employee benefit plan. In addition, during the Standstill Period, subject to certain exceptions, the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of Ordinary Shares or Ordinary Share Equivalents (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the Securities Purchase Agreement). The transaction was completed on January 3, 2025.

Consulting Arrangements

CGY Investment Limited

We entered into a consulting agreement with CGY Investment Limited ("CGY") effective on January 10, 2020. Pursuant to this agreement, CGY shall provide certain consultancy, advisory, and management services to the Group on potential investment projects related to health care or R&D platform; CGY Investment Limited is initially entitled to receive HK $104,000 (approximately $13,333) per calendar month plus reimbursement; such monthly service fee is adjusted to HK$171,200 (approximately US$21,949) with effect from March 1, 2022. In August 2023, CGY Investment Limited has agreed to suspended its monthly services fee from August 1, 2023. In November 2023, CGY Investment Limited and the Group reached a mutual agreement to terminate their contractual relationship.

CGY is 50% held by Seng Fun Yee, 25% held by Mandy Lui and 25% held by Adrian Lui (all of who are related to Mr. Lui). Mr. Lui, the former Chief Executive Officer and Executive Director of the Group, controls and/or has substantial influence on the disposition and voting rights of the shares held by his spouse, but no such control over the shares held by his sister or brother. Hence, 50% of the consulting service fee will be deemed as Mr. Lui's compensation.

ACC Medical Limited

We entered into a consulting agreement with ACC Medical Limited ("ACC") effective on December 1, 2020. Pursuant to this agreement, ACC shall provide certain consultancy, advisory, and management services to the Group on clinic operations and other related projects for clinics' business development; ACC Medical Limited is initially entitled to receive HK $101,542 (approximately $13,018) per calendar month plus reimbursement; such monthly service fee is adjusted to HK$143,200 (approximately US$18,359 per month) effective from March 1, 2022. During the year ended December 31, 2023, and 2022, ACC Medical Limited also received $28,615 and $23,275 one-off compensation respectively. The agreement was terminated on June 30, 2023. ACC is wholly owned by Dr. Clark Cheng, who is also the sole director of ACC, the Group's former Chief Medical Officer and Executive Directors.

Administrative Management Services

Libra Sciences Limited

On January 1, 2022, the Group entered into an administrative management services agreement with Libra Sciences Limited. According to the agreement, the Group will provide documentation and administrative services, include but are not limited to human resources and payroll administration, general secretarial and administrative support, and accounting and financial reporting services. The Group is entitled to receive a fixed amount of services fees of HKD 25,000 (approximately $3,205) per calendar month with the expiry date on December 31, 2023. The Group and Libra Sciences Limited mutually agreed to terminate the administrative management service agreement effective as of March 31, 2023.

Employment Agreements

We entered into Appointment Letters with each of our executive officers. The terms of the Appointment Letters for each of our executive officers are consistent with each other, except with regard to the individual's compensation, term of employment and duties and responsibilities, the latter of which coincides with the standard functions normally associated with the given position. In addition to setting forth the individual compensation and such, the appointment letters contain the following material terms:

We may terminate employment for cause, at any time, without advance notice or remuneration, for certain acts of the executive officer, such as conviction or plea of guilty to a felony or any crime involving moral turpitude, negligent or dishonest acts to our detriment, or misconduct or a failure to perform agreed duties. We may also terminate an executive officer's employment without cause upon three-month advance written notice. In such case of termination by us, we will provide severance payments to the executive officer as expressly required by applicable law of the jurisdiction where the executive officer is based. The executive officer may resign at any time with three-month advance written notice.

Each executive officer has agreed to hold, both during and after the termination or expiration of his or her Appointment Letter, in strict confidence and not to use, except as required in the performance of his or her duties in connection with the employment or pursuant to applicable law, any of our confidential information or trade secrets, any confidential information or trade secrets of our clients or prospective clients, or the confidential or proprietary information of any third-party received by us and for which we have confidential obligations.

In addition, each executive officer has agreed to be bound by non-solicitation and non-compete restrictions during the term of his or her employment and typically for one year following the last date of employment. Specifically, each executive officer has agreed not to (i) solicit or entice away from the Company, any person, firm, company or organization that is or shall have been at any time within 12 months prior to termination of employee a customer, client, identified prospective customer or client of the Company or in the habit of dealing with the Company; (ii) employ, solicit or entice away from the Company any person who is or shall have been on the date of or within 12 months prior to termination of employment an employee of the Company; or (iii) assume employment with or provide services to, or otherwise engage in income generating activities with any of our competitors, or engage, whether as principal, partner, licensor or otherwise, any of our competitors, without our express consent.

Some of our Appointment Letters also provide for the executive officer to participate in our mandatory provident fund, which is similar to a pension fund.

Effective on November 27, 2023, we re-appointed Mr. Huen as Chief Executive Officer and Executive Director whereas all other previous employment terms and conditions remain unchanged. Under the previous appointment letter, we paid Mr. Huen approximately USD27,308 per month. The appointment letter can be earlier terminated by either party with two-months' written notice.

Effective on August 8, 2024, we appointed Mr. Wong as our Head of Finance. Under the appointment letter, the appointment carry no remuneration but is subject to change based on subsequent discussion between Mr. Wong and the Company. The appointment letter can be earlier terminated by either party with one-month' written notice.

See "Item 6. Directors, Senior Management and Employees — C. Board Practices — Employment Agreements".

C. Interests of Experts and Counsel

Not applicable.

Item 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

We have appended consolidated financial statements filed as part of this annual report.

Legal Proceedings

From time to time, we are subject to legal proceedings, investigations and claims incidental to the conduct of our business.

On December 16, 2024, the Company received a letter from Carey Olsen with a Summons with Notice dated September 3, 2024, taken out by Karen Cheung (a/k/a Wing TSZ Cheung) as plaintiff against, among others, the Company as defendant in the Supreme Court of the State of New York County of New York, in relation to an action to recover financial losses sustained by the plaintiff (the "Case"). The Case is at the very early stages of litigation and although we intend to defend the lawsuit, there can be no assurance regarding the ultimate outcome of this case. Due to the inherent uncertain nature of litigation, the ultimate outcome or actual cost of settlement may materially vary from estimates. If management's estimates prove incorrect, current reserves could be inadequate and we could incur a charge to earnings which could have a material adverse effect on our results of operations, financial condition, net worth, and cash flows.

Dividend Policy

We have never declared or paid cash dividends to our shareholders, and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our Board of Directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our Board of Directors may deem relevant.

Under Cayman Islands law, dividends may be declared and paid only out of funds legally available therefor, namely out of either profit or our share premium account, and provided further that a dividend may not be paid if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business.

B. Significant Changes

Except as disclosed elsewhere in this annual report, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

Item 9. THE OFFER AND LISTING

A. Offering and Listing Details.

Our Class A Ordinary Shares are currently listed on NASDAQ Capital Market under the symbol “APM.”

B. Plan of Distribution

Not applicable.

C. Markets

Our Class A Ordinary Shares are currently listed on NASDAQ Capital Market under the symbol “APM.”

Following a comprehensive review of the trading volume, costs and administrative requirements related to its listing on Euronext Paris, Company voluntary delisted its Class A Ordinary Shares (ISIN KYG6096M1226) from Euronext Paris as of July 5, 2023.

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. Amended and Restated Memorandum and Articles of Association

We are a Cayman Islands exempted company with limited liability and our affairs are governed by our Third Amended and Restated Memorandum and Articles of Association (the “Memorandum and Articles”), the Companies Law, the common law of the Cayman Islands, our corporate governance documents and rules and regulations of the stock exchange on which are shares are traded. The Memorandum and Articles of the Company is filed herein as Exhibit 1.2 to this annual report and is hereby incorporated by reference into this annual report. You may refer to Exhibit 2.3 for a detailed disclosure of description of our securities registered under Section 12 of the Exchange Act of 1934, as amended, of the Memorandum and Articles.

As of the date hereof, the authorized share capital of the Company is $100,000,000.00, divided into 9,999,996,000,000 Class A Ordinary Shares with a nominal or par value of $0.00001 each and 4,000,000 Class B Ordinary Shares with a nominal or par value of $0.00001 each. As of the date hereof, 4,950,322 Class A Ordinary Shares and 1,796,934 Class B Ordinary Shares are issued and outstanding. All of our issued and outstanding Class A Ordinary Shares and Class B Ordinary Shares are fully paid.

At the February 21, 2023, special extraordinary meeting of shareholders, the shareholders approved by a special resolution an amendment and restatement of the Company's Second Amended and Restated Memorandum and Articles of Association (the "M&A") in the form of the Third Amended and Restated Memorandum and Articles of Association, to reflect (i) the merger between the Company and Aptorum Group Cayman Limited, a newly established wholly owned subsidiary of the Company, whereby the Company would be the surviving company (the "Merger") pursuant to a plan of merger, which also forces a change in par value to Ordinary Shares of the Company from USD10 to USD0.00001 (the "Plan of Merger"); (ii) the voting rights of the Class B Ordinary Shares be increased from 10 votes per share to 100 votes per share; (iii) a staggered board of directors consisting of three (3) classes, such that only one (1) class is subject to re-election each year; (iv) to increase the number of Class A Ordinary Shares authorized; (v) reducing the vote required for class consent from two-thirds (2/3) to a simple majority; and (vi) to decrease the number of days for effective service by post to shareholders from 14 days to 3 days (collectively, the "Amendments of M&A") and that the Third Amended and Restated Memorandum and Articles of Association be adopted as the Memorandum and Articles of Association of the Company, to the exclusion of the existing M&A with effect from February 21, 2023, which is the date of the registration of the Merger with the Registrar of Companies of the Cayman Islands.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company" or elsewhere in this annual report.

D. Exchange Controls

There are no governmental laws, decrees, regulations or other legislation in the Cayman Islands, the United Kingdom or Hong Kong 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, other than withholding tax requirements. There is no limitation imposed by Cayman Islands law, the United Kingdom law, Hong Kong law or our articles of association on the right of non-residents to hold or vote shares.

E. Taxation

Cayman Islands Tax Considerations

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or brought within, the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties which are applicable to any payments made by or to our Company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our Class A Ordinary Shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of our Class A Ordinary Shares, nor will gains derived from the disposal of our Class A Ordinary Shares be subject to Cayman Islands income or corporation tax.

No stamp duty is payable in respect of the issue of our Class A Ordinary Shares or on an instrument of transfer in respect of our Class A Ordinary Shares except on instruments executed in, or brought within, the jurisdiction of the Cayman Islands.

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

The following is a description of the material U.S. federal income tax consequences to U.S. Holders (as defined below) of purchasing, owning and disposing of Class A Ordinary Shares. It is not a comprehensive description of all U.S. federal income tax considerations that may be relevant to a particular person's decision to acquire Class A Ordinary Shares. This discussion applies only to a U.S. Holder that holds a Class A Ordinary Share as a capital asset for U.S. federal income tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, non-U.S. tax consequences, federal estate or gift tax consequences, alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare Contribution Tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks and other financial institutions;
- insurance companies;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding Class A Ordinary Shares as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the Class A Ordinary Shares;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- tax exempt entities, including "individual retirement accounts" and "Roth IRAs";
- former citizens or long-term residents of the United States;
- entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- regulated investment companies or real estate investment trusts;
- persons who acquired our Class A Ordinary Shares pursuant to the exercise of an employee share option or otherwise as compensation;
- persons that own or are deemed to own ten percent or more of our shares; and
- persons holding Class A Ordinary Shares in connection with a trade or business conducted outside the United States.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds Class A Ordinary Shares, the U.S. federal income tax treatment of such partnership and each partner thereof will generally depend on the status of the partner and the activities of the partnership. Partnerships holding Class A Ordinary Shares and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of purchasing, holding and disposing of Class A Ordinary Shares.

The discussion is based on the Code, the Treasury Regulations issued thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. Such change could materially and adversely affect the tax consequences described below.

For purposes of this discussion, a "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of Class A Ordinary Shares and that is:

(1) an individual citizen or resident of the United States;

(2) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

(3) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) a trust, (i) if a court within the United States is able to exercise primary supervision over its administration and one or more "U.S. persons" (within the meaning of the Code) have the authority to control all of its substantial decisions, or (ii) if a valid election is in effect for the trust to be treated as a U.S. person.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local and foreign tax consequences of purchasing, owning and disposing of Class A Ordinary Shares in their particular circumstances.

Taxation of Distributions

Subject to the discussion below under "Passive Foreign Investment Company Rules," a U.S. Holder will be required to include in gross income as dividend income the gross amount of any distributions paid on Class A Ordinary Shares (including any amount of taxes withheld), other than certain *pro rata* distributions of Class A Ordinary Shares, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits would be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the Class A Ordinary Shares and thereafter as a gain from the sale of the Class A Ordinary Shares. However, because we do not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends.

In case of a U.S. Holder that is a corporation, dividends paid on the Class A Ordinary Shares will be subject to regular corporate rates and will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations.

Dividends received by an individual, trust or estate will be subject to taxation at standard tax rates. A reduced income tax rate applies to dividends paid by a "qualified foreign corporations" (if certain holding period requirements and other conditions are met). A non-U.S. corporation generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which includes an exchange of information program or (ii) with respect to any dividend it pays on stock which is readily tradable on an established securities market in the United States. US. Treasury Department guidance indicates that our Class A Ordinary Shares, which is listed on the NASDAQ Capital Market is readily tradable on an established securities market in the United States. There can be no assurance, however, that our Class A Ordinary Shares will be considered readily tradable on an established securities market in later years.

Non-corporate U.S. Holders will not be eligible for reduced rates of taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year (See "Item 10. Additional Information – E. Taxation – Material U.S. Federal Income Tax Considerations for U.S. Holders – Passive Foreign Investment Company Rules" below).

A U.S. Holder may be eligible, subject to a number of complex limitations, to claim a foreign tax credit in respect of any foreign withholding taxes imposed on dividends received on the Class A Ordinary Shares. A U.S. Holder who does not elect to claim a foreign tax credit for foreign income tax withheld may instead claim a deduction for U.S. federal income tax purposes in respect of such withholding, but only for a year in which such investor elects to do so for all creditable foreign income taxes. For purposes of calculating the foreign tax credit limitation, dividends paid by us will, depending on the circumstances of the U.S. Holder, be either general or passive income.

While we do not expect to pay dividends in the near future, in the event any dividends are paid and if a dividend is paid in non-U.S. currency, it must be included in a U.S. Holder's income as a U.S. dollar amount based on the exchange rate in effect on the date such dividend is actually or constructively received, regardless of whether the dividend is in fact converted into U.S. dollars. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. Holder generally will not recognize a foreign currency gain or loss. If the non-U.S. currency is converted into U.S. dollars on a later date, however, the U.S. Holder must include in income any gain or loss resulting from any exchange rate fluctuations. Such gain or loss will generally be ordinary income or loss and will be from sources within the United States for foreign tax credit limitation purposes. U.S. Holders should consult their own tax advisors regarding the tax consequences to them if we pay dividends in non-U.S. currency.

Sale or Other Taxable Disposition of Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Rules," gain or loss realized on the sale or other taxable disposition of Class A Ordinary Shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the Class A Ordinary Shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the Class A Ordinary Shares disposed of and the amount realized on the disposition. Long-term capital gain of a non-corporate U.S. Holder is generally taxed at preferential rates. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations. U.S. Holders are urged to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on the disposition of Class A Ordinary Shares, including the availability of the foreign tax credit under an investor's own particular circumstances.

A U.S. Holder that receives non-U.S. currency on the disposition of the Class A Ordinary Shares will realize an amount equal to the U.S. dollar value of the foreign currency received on the date of disposition (or in the case of cash basis and electing accrual basis taxpayers, the settlement date) whether or not converted into U.S. dollars at that time. Very generally, the U.S. Holder will recognize currency gain or loss if the U.S. dollar value of the currency received on the settlement date differs from the amount realized with respect to the Class A Ordinary Shares. Any currency gain or loss on the settlement date or on any subsequent disposition of the foreign currency generally will be U.S.-source ordinary income or loss.

Passive Foreign Investment Company Rules

Special U.S. federal income tax rules apply to a U.S. Holder that holds stock in a foreign corporation classified as a PFIC for U.S. federal income tax purposes. In general, a non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income for such taxable year is passive income (e.g., dividends, interest, capital gains and rents derived other than in the active conduct of a rental business); or

- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation in which we own, directly or indirectly, 25% or more (by value) of the equity.

A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change. In particular, the total value of our assets generally will be calculated using the market price of our Class A Ordinary Shares, which may fluctuate considerably. Fluctuations in the market price of our Class A Ordinary Shares may result in our being a PFIC for any taxable year.

Due to the amount of cash and cash equivalents and investments that we had on hand during our year ending December 31, 2024, we believe that we were classified as a PFIC for that tax year. Depending on the future composition and value of our assets, we may be classified as a PFIC for future years.

If we were to be classified as a PFIC, a U.S. Holder would be subject to different taxation rules depending on whether the U.S. Holder (i) takes no action, (ii) makes an election to treat us as a "Qualified Electing Fund" (a "QEF election") or (iii) if permitted, makes a "mark-to-market" election with respect to our Class A Ordinary Shares. A U.S. Holder of our Class A Ordinary Shares will also be required under applicable Treasury Regulations to file an annual information return (Form 8621) containing information regarding our company. Additional explanations of the PFIC rules are set forth below: this material is complex and may affect different U.S. Holders differently. Accordingly, U.S. Holders should consult their own tax advisors about the consequences of our company being classified as a PFIC and about what steps, if any, they might take to lessen the tax impact of our PFIC status on them.

A U.S. Holder who does not make a timely QEF or mark-to-market election (a "Non-Electing Holder"), as discussed below, will be subject to special tax rules with respect to any "excess distribution" that you receive and any gain you realize from a sale or other disposition (including a pledge) of Class A Ordinary Shares. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the Class A Ordinary Shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the Class A Ordinary Shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

It should be noted that, until such time as we make a distribution, there are no tax consequences to Non-Electing Holders. However, if we ever did make a distribution it would in all likelihood be an excess distribution (because we would not have previously made any distributions to holders of Class A Ordinary Shares). At that point, and for all subsequent distributions, the rules described above would apply to Non-Electing Holders. The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the Class A Ordinary Shares cannot be treated as capital, even if you hold the Ordinary Shares as capital assets.

Certain elections may be available that would result in alternative treatments. The adverse consequences of owning stock in a PFIC could be mitigated if a U.S. Holder makes a valid QEF election (a U.S. Holder which we refer to as an "Electing Holder") which, among other things, would require the Electing Holder to include currently in income its pro rata share of the PFIC's net capital gain and ordinary earnings, if any, for our taxable year that ends with or within the taxable year of the Electing Holder, regardless of whether or not the Electing Holder actually received distributions from us. When an Electing Holder makes a QEF election, its adjusted tax basis in our Class A Ordinary Shares is increased to reflect taxed but undistributed earnings and profits. Distributions of earnings and profits that had been previously taxed will result in a corresponding reduction in the adjusted tax basis in our Class A Ordinary Shares and will not be taxed again once distributed. An Electing Holder would generally recognize capital gain or loss on the sale, exchange or other disposition of our Class A Ordinary Shares.

A U.S. Holder can make a QEF election with respect to any year that we are a PFIC by filing IRS Form 8621 with its U.S. federal income tax return. This election must be made by the deadline (including extensions) for filing the U.S. Holder's federal tax return for the year in question. U.S. Holders should discuss their election alternatives with their own tax advisors. Once an election is made, the Electing Holder is subject to the QEF rules for as long as we are a PFIC.

It should be noted that in order to make a QEF election a U.S. Holder needs information from us concerning our PFIC status and our financial results for the year. We cannot assure our U.S. Holders that we will provide such information.

As an alternative to making a QEF election, a U.S. Holder may make a "mark-to-market" election with respect to our Class A Ordinary Shares provided our Class A Ordinary Shares are treated as "marketable stock." The Class A Ordinary Shares generally will be treated as marketable stock if they are regularly traded on a "qualified exchange or other market" (within the meaning of applicable Treasury Regulations) on at least 15 days during each calendar quarter (other than in de minimis amounts).

If a U.S. Holder makes an effective mark-to-market election, for each taxable year that we are a PFIC, the U.S. Holder will include as ordinary income the excess of the fair market value of its Class A Ordinary Shares at the end of the year over its adjusted tax basis in the Class A Ordinary Shares. You will be entitled to deduct as an ordinary loss in each such year the excess of your adjusted tax basis in the Class A Ordinary Shares over their fair market value at the end of the year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Holder's adjusted tax basis in the Class A Ordinary Shares will be increased by the amount of any income inclusion and decreased by the amount of any deductions under the mark-to-market rules. In addition, upon the sale or other disposition of your Class A Ordinary Shares in a year that we are PFIC, any gain will be treated as ordinary income and any loss will be treated as ordinary loss, but only to the extent of the net amount of previously included income as a result of the mark-to-market election.

If a U.S. Holder makes a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the Class A Ordinary Shares are no longer regularly traded on a qualified exchange or other market, or the IRS consents to the revocation of the election. You are urged to consult your tax advisor about the availability of the mark-to-market election, and whether making the election would be advisable in your particular circumstances.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with Respect to Foreign Financial Assets

Certain U.S. Holders may be required to report information relating to the Class A Ordinary Shares, subject to certain exceptions (including an exception for Class A Ordinary Shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their purchase, ownership, and disposition of the Class A Ordinary Shares.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We have previously filed the Registration Statement with the SEC.

We are subject to the periodic reporting and other informational requirements of the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F within four months after the end of each fiscal year. Copies of reports and other information, when so filed, may be inspected without charge, and may be obtained at prescribed rates at the public reference facilities maintained by the SEC at Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information regarding the Washington, D.C. Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system. As a foreign private issuer, we are exempt from the rules of the Exchange Act prescribing, among other things, the furnishing and content of proxy statements to shareholders, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

We also maintain a corporate website at www.aptorumgroup.com. Information contained on, or that can be accessed through, our website does not constitute a part of this report.

I. Subsidiary Information

For a listing of our subsidiaries, see "Item 4. Information on the Company — A. History and Development of the Company."

J. Annual Report to Security Holders.

Not applicable.

Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For purposes of Item 11, reference to the "Group" means Aptorum Group Limited and all of its subsidiaries.

Foreign Exchange Risk

Currency risk is the risk that the value of financial assets or liabilities will fluctuate due to changes in foreign exchange rates.

Currency risk sensitivity analysis

At December 31, 2024, and 2023, the Group has no significant foreign currency risk because most of the transactions are denominated in Hong Kong dollar or the United States dollar. Since the Hong Kong dollar is pegged to the United States dollar, the Group's exposure to foreign currency risk in respect of the balances denominated in Hong Kong dollars is considered to be minimal.

Credit Risk

Financial assets which potentially subject the Group to concentrations of credit risk consist principally of bank deposits and balances.

The Group takes on exposure to credit risk on cash balances majority held with HSBC for the purposes of payments of Group expenses. The risk of default is considered minimal as the Group considers HSBC is well established with high credit rating.

Liquidity Risk

Liquidity risk is the risk that the Group will encounter difficulty in raising funds to meet commitments associated with financial assets and liabilities. Liquidity risk may result from an inability to sell a financial asset quickly at an amount close to its fair value.

The Group invested in private equities which are generally unquoted and not readily marketable before its restructuring to an operating company. After the restructuring in 2017, the Group generally does not acquire new investments in unlisted securities that cannot be readily disposed of to minimize the liquidity risk. Investment of the Group's assets in unquoted securities may restrict the ability of the Group to dispose of its investment at a price and time it wishes to do so.

Interest Rate Risk

Interest rate risk arises from the possibility that changes in interest rates will affect future cash flows or the fair values of financial instruments.

Interest rate risk sensitivity analysis

The Group's cash and time deposits held with banks are exposed to interest rate risk. However, Management considers the risk on cash and time deposits to be minimal as they are short-term with terms less than three months.

Inflation Risk

In recent years, inflation has not had a material impact on our results of operations.

Item 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Items 12.D.3 and 12.D.4 of this Item 12 is not applicable, as the Company does not have any American Depositary Shares; all other applicable information required by this Item 12 is included in Exhibit 2.3.

Part II

Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

Item 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

See “Item 10. Additional Information” for a description of the rights of securities holders, which remain unchanged.

Item 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and our chief financial accounting officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures, which is defined in Rules 13a-15(e) of the Exchange Act, as of December 31, 2024. Based on that evaluation, our chief executive officer and chief financial accounting officer concluded that our disclosure controls and procedures, as of December 31, 2024, were not effective at the reasonable assurance level due to the material weakness described below.

(b) Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with Generally Accepted Accounting Principles (GAAP) in the United States of America and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of our company’s assets that could have a material effect on the consolidated financial statements.

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

As required by Section 404 of the Sarbanes-Oxley Act of 2002 and related rules as promulgated by the Securities and Exchange Commission, our management including our Chief Executive Officer and Chief Financial Accounting Officer assessed the effectiveness of internal control over financial reporting as of December 31, 2023, using the criteria set forth in the report “Internal Control—Integrated Framework (2013)” published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

In connection with the previous audit of our financial statements for the year ended December 31, 2024, we and our independent registered public accounting firm identified one material weakness in our internal control over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board of the United States. The material weakness identified was the lack of dedicated resources to take responsibility for the finance and accounting functions and the preparation of financial statements in compliance with generally accepted accounting principles in the United States, or U.S. GAAP.

Since 2019, we took actions to remediate the abovementioned material weakness, and we believe we have remediated the material weakness by implementing the following measures:

- provide trainings to staff regarding to the preparation of financial statements in compliance with generally accepted accounting principles in the United States;
- change to a new and well-established accounting system to enhance effectiveness and financial and system control;
- establish clear roles and responsibilities for accounting and financial reporting staff to address finance and accounting issues; and
- continue to monitor the improvement on internal control over financial reporting.

However, since we are still in the process of replenishing and building up a qualified finance and accounting team with sufficient dedicated resources, our management assessed that the deficiency related to the lack of dedicated resources to take responsibility for the finance and accounting functions and the preparation of financial statements in compliance with generally accepted accounting principles in the United States, or U.S. GAAP, still existed as of December 31, 2024.

We cannot assure you that we will not identify additional material weaknesses or significant deficiencies in the future. See "Item 3. Key Information—D. Risk Factors— Risks Related to Our Industry, Business and Operation — If we fail to establish and maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired."

Notwithstanding there is a material weakness identified as described above, we believe that our consolidated financial statements contained in this annual report on Form 20-F fairly present our financial position, results of operations and cash flows for the years covered thereby in all material respects.

(c) Attestation Report of the Company's Registered Public Accounting Firm

We did not include an attestation report of the company's registered public accounting firm due to rules of the SEC where domestic and foreign registrants that are non-accelerated filers, which we are, are not required to provide the auditor attestation report.

(d) Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [RESERVED]

Item 16A. AUDIT COMMITTEE FINANCIAL EXPERT

We have one financial expert as of the date of this report. Our Board of Directors has determined that Douglas Arner, Chair of our audit committee, qualifies as an "audit committee financial expert" as defined in the SEC rules and satisfies the financial sophistication requirements of The NASDAQ Capital Market. Douglas Arner is "independent" as that term is defined in the rules of the SEC and the applicable rules of the NASDAQ Capital Market.

Item 16B. CODE OF ETHICS

The Company's Code of Ethics became effective on the effective date of the Registration Statement. The Code of Ethics is incorporated by reference to exhibit 14.1 of the Registration Statement.

Item 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by our principal external auditors, for the periods indicated.

	For the years ended December 31,	
	2024	2023
	(In thousand)	
Audit fees	$ 308	$ 363
Audit-related fees	-	-
Tax fees	-	-
All other fees	-	-
Total	$ 308	$ 363

“Audit fees” represents the aggregate fees billed or to be billed for each of the fiscal years listed for professional services rendered by our principal auditor for the audit of our annual financial statements or services that in connection with statutory and regulatory filings or engagements for those fiscal years.

“Audit-related fees” are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under audit fees.

“Tax fees” include fees for professional services rendered by our principal auditor for tax compliance and tax advice on actual or contemplated transactions.

“Other fees” include fees for services rendered by our independent registered public accounting firm with respect to other matters not reported under “Audit fees,” “Audit-related fees” and “Tax fees”.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by our principal auditor including audit services, audit-related services, tax services and other services.

Item 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

Item 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

Item 16F. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT

Not applicable.

Item 16G. CORPORATE GOVERNANCE

See “Item 6. Directors, Senior Management and Employees” for more information.

Item 16H. MINE SAFETY DISCLOSURE

Not applicable.

Item 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

Item 16J. INSIDER TRADING POLICIES

Not applicable.

Item 16K. CYBERSECURITY

Our business activity to date has been focusing on the healthcare field and have not yet adopted formal cybersecurity risk management programs or formal processes for assessing cybersecurity risks. We understand the importance of managing material risks from cybersecurity threats and are committed, as part of our continuing growth, to implementing and maintaining an adequate information security program to manage such risks and safeguard our systems and data.

We currently manage our cybersecurity risk through a variety of practices that are applicable to all users of our information technology and information assets, including our employees and contractors. We use a combination of technology, policies, training, and monitoring to promote security awareness and prevent security incidents.

Due to the early stage of development of our projects, we believe have limited exposure to cyber threats other than emails and project data storage.

We have not, as of the date of this annual report, experienced a cybersecurity threat or incident in the last three years, that materially affected or is reasonably likely to affect our business, results of operations, or financial condition. However, there can be no guarantee that we will not experience such an incident in the future.

Our board of directors oversees cybersecurity risk as part of its role of overseeing enterprise-wide risk.

Part III

Item 17. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 18.

Item 18. FINANCIAL STATEMENTS

The consolidated financial statements of Aptorum Group Limited, and its subsidiaries are included at the end of this annual report.

Item 19. EXHIBITS

EXHIBIT INDEX

Exhibit No.	Description
1.1	Third Amended and Restated Articles of Association, as amended [21]
2.1	Registrant's Specimen Certificate for Ordinary Shares [21]
2.2	Form of Underwriter's Warrant+++
2.3	Description of Securities registered under Section 12 of the Exchange Act of 1934, as amended [21]
2.4	Form of Warrant+
4.1	Form of Underwriting Agreement+++
4.2	Appointment Letter between the Company and Ian Huen (Founder, Chief Executive Officer & Executive Director), dated September 25, 2017*
4.3	Appointment letter between the Company and Ian Huen (Non-Executive Director), dated May 27, 2022 [21]
4.4	Appointment letter between the Company and Ian Huen (Executive Director), dated November 20, 2023 [25]
4.5	Reserved.
4.6	Reserved.
4.7	Employment Agreement between the Company and Justin Wu (Independent Non-Executive Director), dated September 18, 2017*
4.8	Employment Agreement between the Company and Douglas Arner (Independent Non-Executive Director), dated February 13, 2018*
4.9	2017 Share Option Plan, as amended [15]
4.10	Service Agreement Between Covar Pharmaceuticals Incorporated and Videns Incorporation Limited*
4.11	Exclusive Patent License Agreement for ALS-4 dated October 18, 2017[3]
4.12	First Amendment to Exclusive License Agreement for ALS-4 dated June 7, 2018*
4.13	Second Amendment to Exclusive License Agreement for ALS-4 dated July 10, 2019[6]
4.14	Exclusive License Agreement for ALS-4 dated January 11, 2019[4]

4.15	Master Collaboration Agreement by and between the Company, A*ccelerate Technologies Pte. Ltd, and AENEAS CAPITAL LIMITED dated April 24, 2019[1]
4.16	Bond Repurchase Agreement dated April 24, 2019[1]
4.17	Form of Line of Credit Agreement [2]
4.18	Form of Promissory Note [2]
4.19	Form of Securities Purchase Agreement+
4.20	Evaluation Agreement with Illumina Inc. (portions of the exhibit have been omitted because they (i) are not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.) [7]
4.21	Placement Agency Agreement, dated February 25, 2020, between the Company and Alliance Global Partners [8]
4.22	Form of Securities Purchase Agreement [8]
4.23	Form of Warrant [8]
4.24	Form of Securities Purchase Agreement dates as of September 29, 2020, by and among the Company and the purchasers named therein [9]
4.25	Form of Warrant [9]
4.26	Form of Pre-Funded Warrant [9]
4.27	Form of Placement Agent Warrant [9]
4.28	Exclusive License Agreement with Accelerate Technologies Pte Ltd.'s dated September 25, 2020[11, 12]
4.29	Sales Agreement, dated March 26, 2021, between the Company and H.C. Wainwright [10]
4.30	Share Subscription and Shareholders Agreement dated as of September 25, 2020[11,12]
4.31	Private Placement Shares Purchase Agreement with Jurchen Investment Corporation [14]
4.32	Reserved.
4.33	Reserved.
4.34	Reserved.
4.35	Form of Securities Purchase Agreement [18]
4.36	Non-binding Letter of Intent [20]
4.37	Securities Purchase Agreement and Form of convertible note dated September 11, 2023 [22]
4.38	Securities Purchase Agreement dated June 28, 2023 [23]
4.39	Securities Purchase Agreement dated January 2, 2025 [24]
8.1	List of Subsidiaries [21]
12.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a)**
12.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a)**
13.1	Certification of Chief Executive Officer and Chief 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 Marcum Asia CPAs LLP**
97.1	Policy for the Recovery of Erroneously Awarded Compensation [25]
99.1	Code of Business Ethics*
101.INS	Inline XBRL Instance Document**
101.SCH	Inline XBRL Taxonomy Extension Schema Document**
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document**
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document**
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document**
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document**
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) **

*** Furnished with this annual report on Form 20-F
** Filed with this annual report on Form 20-F
* Incorporated by reference to our Registration Statement Filed on Form F-1 on September 5, 2018
+++ Incorporated by reference to our Registration Statement Filed on Form F-1 on November 15, 2018
++ Incorporated by reference to our Current Report on Form 6-K filed on April 1, 2019
+ Incorporated by reference to our Current Report on Form 6-K filed on February 26, 2020

(1) Incorporated by reference to our Current Report on Form 6-K filed on April 24, 2019.

(2) Incorporated by reference to our Current Report on Form 6-K filed on August 14, 2019.

(3) Incorporated by reference to our Registration Statement Filed on Form F-1 on September 5, 2018; portions of the exhibit were previously omitted in reliance on the confidential treatment provisions available pursuant to revised paragraph 4(a) of Instructions as to Exhibits of Form 20-F.

(4) Incorporated by reference to our annual report on Form 20-F filed on April 15, 2019; portions of the exhibit were previously omitted in reliance on the confidential treatment provisions available pursuant to revised paragraph 4(a) of Instructions as to Exhibits of Form 20-F.

(5) Incorporated by reference to our Annual Report on Form 20-F filed on April 15, 2019.

(6) Incorporated by reference to our Annual Report on Form 20-F filed on April 29, 2020. Certain information from this exhibit has been excluded from this exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

(7) Incorporated by reference to our Current Report on Form 6-K filed on January 25, 2021; portions of the exhibit were omitted because they (i) are not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

(8) Incorporated by reference to our Current Report on Form 6-K filed on February 26, 2020.

(9) Incorporated by reference to our Current Report on Form 6-K filed on October 2, 2020.

(10) Incorporated by reference to our Current Report on Form 6-K filed on March 26, 2021.

(11) Certain information from this exhibit has been excluded from this exhibit because it both (i) is not material and (ii) is the type that the registrant treats as private or confidential.

(12) Incorporated by reference to our Annual Report on Form 20-F filed on April 19, 2021.

(13) Incorporated by reference to our Current Report on Form 6-K filed on November 17, 2021.

(14) Incorporated by reference to our Current Report on Form 6-K filed on May 26, 2021.

(15) Incorporated by reference to our Current Report on Form 6-K filed on November 17, 2021.

(16) Incorporated by reference to our Current Report on Form 6-K filed on July 11, 2022.

(17) Reserved.

(18) Incorporated by reference to our Current Report on Form 6-K filed on December 9, 2022.

(19) Incorporated by reference to our Annual Report on Form 20-F/A filed on January 17, 2023.

(20) Incorporated by reference to our Current Report on Form 6-K filed on March 27, 2023.

(21) Incorporated by reference to our annual report on Form 20-F filed on April 28, 2023.

(22) Incorporated by reference to our Current Report on Form 6-K filed on September 11, 2023.

(23) Incorporated by reference to our Current Report on Form 6-K filed on June 30, 2023.

(24) Incorporated by reference to our Current Report on Form 6-K filed on January 7, 2025.

(25) Incorporated by reference to our Annual Report on Form 20-F filed on April 30, 2024.

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.

Aptorum Group Limited

Date: April 30, 2025

By: /s/ Ian Huen
Ian Huen
Chief Executive Officer,
Chairman of the Board of Directors
(Principal Executive Officer)

Date: April 30, 2025

By: /s/ Wong Kwok Kuen
Wong Kwok Kuen
Head of Finance
(Principal Financial Officer)

APTORUM GROUP LIMITED
Financial Statements

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MARCUMASIA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Aptorum Group Limited

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aptorum Group Limited (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum Asia CPAs LLP
Marcum Asia CPAs LLP

We have served as the Company's auditor since 2017.
New York, NY
April 30, 2025

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APTORUM GROUP LIMITED
CONSOLIDATED BALANCE SHEETS
December 31, 2024 and 2023
(Stated in U.S. Dollars, except for number of shares)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 874,238	$ 2,005,351
Accounts receivable	-	47,709
Amounts due from related parties, net	-	961
Other receivables and prepayments	85,316	422,071
Total current assets	959,554	2,476,092
Property and equipment, net	-	1,663,926
Operating lease right-of-use assets, net	-	182,057
Long-term investments, net	15,098,846	16,098,846
Intangible assets, net	-	147,347
Long-term deposits	71,823	71,823
Total Assets	$ 16,130,223	$ 20,640,091
LIABILITIES AND EQUITY		
LIABILITIES		
Current liabilities:		
Amounts due to related parties	$ 79,644	$ 79,180
Accounts payable and accrued expenses	918,611	1,894,341
Operating lease liabilities, current	102,225	125,232
Convertible notes to a related party	3,238,500	-
Total current liabilities	4,338,980	2,098,753
Operating lease liabilities, non-current	14,182	99,485
Convertible notes to a related party	-	3,058,500
Total Liabilities	$ 4,353,162	$ 5,256,738
Commitments and contingencies		-
EQUITY		
Class A Ordinary Shares ($0.00001 par value, 9,999,996,000,000 shares authorized, 3,811,823 shares issued and outstanding as of December 31, 2024; 2,937,921 shares issued and outstanding as of December 31, 2023)	$ 37	$ 31
Class B Ordinary Shares ($0.00001 par value; 4,000,000 shares authorized, 1,796,934 shares issued and outstanding as of December 31, 2024; 2,243,776 shares issued and outstanding as of December 31, 2023)	18	22
Additional paid-in capital	93,474,825	93,018,528
Accumulated other comprehensive income (loss)	89,162	(10,623)
Accumulated deficit	(72,429,528)	(68,161,722)
Total equity attributable to the shareholders of Aptorum Group Limited	21,134,514	24,846,236
Non-controlling interests	(9,357,453)	(9,462,883)
Total equity	11,777,061	15,383,353
Total Liabilities and Equity	$ 16,130,223	$ 20,640,091

See accompanying notes to the consolidated financial statements.

APTORUM GROUP LIMITED
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For Years Ended December 31, 2024, 2023 and 2022
(Stated in U.S. Dollars, except for number of shares)

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue			
Healthcare services income	$ -	$ 431,378	$ 1,295,889
Operating expenses			
Cost of healthcare services	-	(420,812)	(1,215,824)
Research and development expenses	(2,195,161)	(5,198,329)	(9,219,595)
General and administrative fees	(669,486)	(1,930,637)	(5,220,405)
Legal and professional fees	(803,285)	(2,538,161)	(2,888,140)
Other operating expenses	(272,609)	(1,067,690)	(261,038)
Total operating expenses	(3,940,541)	(11,155,629)	(18,805,002)
Other (expense) income, net			
Loss on investments in marketable securities, net	-	(9,266)	(134,134)
Unrealized gain from fair value change of the long-term investments, net	-	6,431,088	6,108,872
Impairment loss of long-term investment	(1,000,000)	(77,200)	(520,821)
Interest (expense) income, net	(146,924)	(121,145)	146,588
Gain on disposal of subsidiaries	703	-	-
Government subsidies	928,461	123,015	335,499
Sundry income	564	36,784	48,007
Total other (expense) income, net	(217,196)	6,383,276	5,984,011
Net loss	(4,157,737)	(4,340,975)	(11,525,102)
Net (loss) income attributable to non-controlling interests	(110,069)	1,516,328	1,725,542
Net loss attributable to Aptorum Group Limited	$ (4,267,806)	$ (2,824,647)	$ (9,799,560)
Net loss per share attributable to Aptorum Group Limited			
- Basic[1]	$ (0.78)	$ (0.62)	$ (2.75)
- Diluted[1]	$ (0.78)	$ (0.62)	$ (2.75)
Weighted-average shares outstanding			
- Basic[1]	5,453,103	4,521,133	3,569,484
- Diluted[1]	5,453,103	4,521,133	3,569,484
Net loss	$ (4,157,737)	$ (4,340,975)	$ (11,525,102)
Other comprehensive income (loss)			
Exchange differences on translation of foreign operations	99,785	(44,430)	35,826
Other comprehensive income (loss)	99,785	(44,430)	35,826
Comprehensive loss	(4,057,952)	(4,385,405)	(11,489,276)
Comprehensive (loss) income attributable to non-controlling interests	(110,069)	1,516,328	1,725,542
Comprehensive loss attributable to the shareholders of Aptorum Group Limited	(4,168,021)	(2,869,077)	(9,763,734)

(1) All per share amounts and shares outstanding for all periods have been retroactively restated to reflect APTORUM GROUP LIMITED's 1 for 10 reverse stock split, which was effective on January 23, 2023.

See accompanying notes to the consolidated financial statements.

APTORUM GROUP LIMITED
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
For Years Ended December 31, 2024, 2023 and 2022
(Stated in U.S. Dollars, except for number of shares)

	Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated deficit	Accumulated Other Comprehensive (loss) income	Non-Controlling interests	Total
	Shares[1]	Amount	Shares[1]	Amount	Amount	Amount	Amount	Amount	Amount
Balance, January 1, 2022	**1,320,241**	**$ 13,202,408**	**2,243,776**	**$ 22,437,754**	**$ 43,506,717**	**$ (55,537,515)**	**$ (2,019)**	**$ (6,101,223)**	**$ 17,506,122**
Issuance of shares to non-controlling interest	-	-	-	-	52,024	-	-	(52,024)	**-**
Share-based compensation	-	-	-	-	1,646,999	-	-	-	**1,646,999**
Exercise of options	6,712	67,120	-	-	102,340	-	-	-	**169,460**
Exchange difference on translation of foreign operation	-	-	-	-	-	-	35,826	-	**35,826**
Net loss	-	-	-	-	-	(9,799,560)	-	(1,725,542)	**(11,525,102)**
Balance, December 31, 2022	**1,326,953**	**$ 13,269,528**	**2,243,776**	**$ 22,437,754**	**$ 45,308,080**	**$ (65,337,075)**	**$ 33,807**	**$ (7,878,789)**	**$ 7,833,305**
Adjustment for change of par value	-	(13,269,514)	-	(22,437,732)	35,707,246	-	-	-	**-**
Issuance of shares to non-controlling interest	-	-	-	-	67,766	-	-	(67,766)	**-**
Issuance of shares in exchange of share options and settlement of liabilities	70,430	1	-	-	3,078,195	-	-	-	**3,078,196**
Issuance of shares for share-based compensation	65,770	1	-	-	176,263	-	-	-	**176,264**
Issuance of shares	215,959	2	-	-	1,575,560	-	-	-	**1,575,562**
Share-based compensation	-	-	-	-	1,088,925	-	-	-	**1,088,925**
Conversion of convertible notes	1,250,000	13	-	-	5,999,987	-	-	-	**6,000,000**
Exercise of share options	791	-	-	-	16,506	-	-	-	**16,506**
Rounding up for reverse stock split	8,018	-	-	-	-	-	-	-	**-**
Exchange difference on translation of foreign operation	-	-	-	-	-	-	(44,430)	-	**(44,430)**
Net loss	-	-	-	-	-	(2,824,647)	-	(1,516,328)	**(4,340,975)**
Balance, December 31, 2023	**2,937,921**	**31**	**2,243,776**	**22**	**93,018,528**	**(68,161,722)**	**(10,623)**	**(9,462,883)**	**15,383,353**
Conversion of Class B Ordinary Shares to Class A Ordinary Shares	446,842	4	(446,842)	(4)	-	-	-	-	**-**
Exercise of options	427,060	2	-	-	451,658	-	-	-	**451,660**
Exchange difference on translation of foreign operation	-	-	-	-	-	-	99,785	-	**99,785**
Disposal of NCI					4,639			(4,639)	**-**
Net loss	-	-	-	-	-	(4,267,806)	-	110,069	**(4,157,737)**
Balance, December 31, 2024	**3,811,823**	**37**	**1,796,934**	**18**	**93,474,825**	**(72,429,528)**	**89,162**	**(9,357,453)**	**11,777,061**

(1) All per share amounts and shares outstanding for all periods have been retroactively restated to reflect APTORUM GROUP LIMITED's 1 for 10 reverse stock split, which was effective on January 23, 2023.

See accompanying notes to the consolidated financial statements.

APTORUM GROUP LIMITED
CONSOLIDATED STATEMENTS OF CASH FLOWS
For Years Ended December 31, 2024, 2023 and 2022
(Stated in U.S. Dollars)

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash flows from operating activities			
Net loss	$ (4,157,737)	$ (4,340,975)	$ (11,525,102)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization and depreciation	255,046	1,125,254	1,207,510
Share-based compensation	-	1,265,189	1,646,999
Loss on investments in marketable securities, net	-	9,266	134,134
Unrealized gain from fair value change of the long-term investments, net	-	(6,431,088)	(6,108,872)
Impairment loss of long-term investment	1,000,000	77,200	520,821
(Gain) loss on disposal of long-lived assets	(58,621)	110,852	205,189
Impairment loss on long-lived assets	1,699,481	750,381	-
Allowance for credit loss of due from a related party	-	521,007	-
Write-off of prepayment and other receivables	45,677	62,369	-
Write-off of accounts receivable	6,280	-	-
Write-down of inventories	-	13,206	-
Gain on disposal of subsidiaries	(703)	-	-
Amortization of right-of-use assets	50,520	252,345	349,031
Interest income	-	-	(235,560)
Interest expense and accretion of convertible debts	180,000	45,266	87,537
Accretion of finance lease obligation	-	-	1,435
Reversal of deferred cash bonus	-	(1,646,228)	-
Changes in operating assets and liabilities			
Accounts receivable	41,349	126,717	(95,704)
Inventories	-	14,516	8,053
Other receivables and prepayments	291,078	227,457	(29,856)
Long-term deposits	-	29,106	19,328
Amounts due from related parties	961	63,050	(46,349)
Amounts due to related parties	464	(8,524)	(6,805)
Accounts payable and accrued expenses	(422,705)	398,635	1,918,751
Operating lease liabilities	(120,824)	(389,365)	(369,505)
Net cash used in operating activities	(1,189,734)	(7,724,364)	(12,318,965)
Cash flows from investing activities			
Purchases of property and equipment	-	(3,015)	(186,916)
Proceeds from disposal of property and equipment	58,621	15,385	-
Disposal of subsidiaries, net of cash disposed		-	-
Proceeds from sales of investment securities	-	93,215	-
Loan to a related party	-	(92,459)	(330,341)
Repayment of loan and interest from a related party	-	611,641	2,962,153
Net cash provided by investing activities	58,621	624,767	2,444,896
Cash flows from financing activities			
Loan from related parties	-	2,500,000	500,000
Proceeds from issuance of subsidiaries shares	-	-	5,360
Proceeds from issuance of Class A Ordinary Shares and warrants	-	1,575,562	-
Exercise of share options	-	16,506	169,460
Loan from a bank	-	-	3,000,000
Repayment of bank loan	-	(3,000,000)	-
Proceeds from issuance of convertible notes	-	3,000,000	3,000,000
Payment of finance lease obligations	-	-	(49,358)
Net cash provided by financing activities	-	4,092,068	6,625,462
Net decrease in cash and cash equivalents and restricted cash	(1,131,113)	(3,007,529)	(3,248,607)
Cash and cash equivalents and restricted cash – Beginning of year	2,005,351	5,012,880	8,261,487
Cash and cash equivalents and restricted cash – End of year	$ 874,238	$ 2,005,351	$ 5,012,880
Supplemental disclosures of cash flow information			
Interest paid	$ -	$ 94,108	$ 64,744
Income taxes paid	$ -	$ -	$ -
Non-cash operating, investing and financing activities			
Right-of-use assets obtained in exchange for new operating lease liabilities	$ -	$ 338,525	$ 549,596
Convertible notes converted to Class A Ordinary Shares	$ -	$ 6,000,000	$ -
Settlement of deferred cash bonus by issuance of share options	$ 451,660	$ 3,078,196	$ -
Reconciliation of cash and restricted cash			
Cash and cash equivalents	$ 874,238	$ 2,005,351	$ 1,882,545
Restricted cash	-	-	3,130,335

Total cash and cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 874,238	$ 2,005,351	$ 5,012,880

See accompanying notes to the consolidated financial statements.

1. ORGANIZATION

The consolidated financial statements include the financial statements of Aptorum Group Limited (the "Company") and its subsidiaries. The Company and its subsidiaries are hereinafter collectively referred to as the "Group".

The Company, formerly known as APTUS Holdings Limited and STRIKER ASIA OPPORTUNITIES FUND CORPORATION, is a company incorporated on September 13, 2010 under the laws of the Cayman Islands with limited liability.

The Company researches and develops life science and biopharmaceutical products within its wholly-owned subsidiary, Aptorum Therapeutics Limited, formerly known as APTUS Therapeutics Limited ("Aptorum Therapeutics") and its indirect subsidiary companies.

Below summarizes the list of the major subsidiaries consolidated as of December 31, 2024:

Name	Incorporation date	Ownership	Place of incorporation	Principle activities
Aptorum Therapeutics Limited ("ATL")	June 30, 2016	100%	Cayman Islands	Research and development of life science and biopharmaceutical products
APTUS MANAGEMENT LIMITED	May 16, 2017	100%	Hong Kong	Provision of management services to its holding company and fellow subsidiaries
Paths Innovations Limited	April 15, 2019	100%	Cayman Islands	Investment holding company
Paths Diagnostics Pte. Limited	June 5, 2019	75%	Singapore	Research and development of life science and biopharmaceutical products
Acticule Life Sciences Limited	June 30, 2017	80%	Cayman Islands	Research and development of life science and biopharmaceutical products

2. GOING CONCERN

The Group reported a net loss of $4,157,737 and net operating cash outflow of $1,189,734 for the year ended December 31, 2024. In addition, the Group had an accumulated deficit of $72,429,528 as of December 31, 2024. On January 2, 2025, the Group entered into a certain securities purchase agreement with certain non-affiliated institutional investors pursuant to which the Group sold 1,535,000 Class A Ordinary Shares of the Group, par value $0.00001 per share at a per share price of $2.00 in a registered direct offering, for gross proceeds of $3,070,000. The Group's operating results for future periods are subject to numerous uncertainties and it is uncertain if the Group will be able to reduce or eliminate its net losses for the foreseeable future. If management is not able to generate significant revenues from its product candidates currently in development, the Group may not be able to achieve profitability. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. In connection with the Company's assessment of going concern considerations in accordance with Financial Accounting Standard Board's Accounting Standards Update ("ASU") 2014-15, "Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern," management has determined that these conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

If the Group is unable to generate sufficient funds to finance the working capital requirements of the Group within the normal operating cycle of a twelve-month period from the date of these consolidated financial statements are issued, the Group may have to consider supplementing its available sources of funds through the following sources:

- other available sources of financing from banks and other financial institutions or private lender; and
- equity financing.

The Company can make no assurances that required financings will be available for the amounts needed, or on terms commercially acceptable to the Company, if at all. If one or all of these events does not occur or subsequent capital raises are insufficient to bridge financial and liquidity shortfall, there would likely be a material adverse effect on the Company and would materially adversely affect its ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Group will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of presentation and consolidation

The consolidated financial statements of the Group are presented on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United Stated Securities and Exchange Commission (the "SEC"), and include the accounts of the Company, its direct and indirect wholly and majority owned subsidiaries. In accordance with the provisions of Accounting Standards Codification ("ASC") 810, Consolidation, the Group also consolidate any variable interest entity ("VIE") of which the Company is the primary beneficiary. The typical condition for a controlling financial interest ownership is holding a majority of the voting interests of an entity; however, a controlling financial interest may also exist in entities, such as VIEs, through arrangements that do not involve controlling voting interests. ASC 810 requires a variable interest holder to consolidate a VIE if that party has the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and the obligation to absorb losses of the VIE that could potentially be significant to the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE. The Group does not consolidate a VIE in which the Company has a majority ownership interest when we are not considered the primary beneficiary. The Company has determined that the Company is the primary beneficiary of the VIE (see Note 13, Variable Interest Entity). The Company evaluate its relationships with the VIE on an ongoing basis to determine whether it becomes the primary beneficiary. All material intercompany balances and transactions have been eliminated in preparation of the consolidated financial statements.

Non-controlling interests

Non-controlling interests are recognized to reflect the portion of the equity of majority-owned subsidiaries which are not attributable, directly or indirectly, to the controlling shareholder. Non-controlling interests are classified as a separate line item in the equity section of the Group's consolidated balance sheets and have been separately disclosed in the Group's consolidated statements of operations and comprehensive loss and consolidated statements of equity to distinguish the interests from that of the Group.

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as income and expenses during the reporting period. Actual results could differ from those estimates. There is no significant accounting estimate.

Foreign currency translation and transaction

USD is the reporting currency. The functional currency of subsidiaries in the Cayman Islands, Seychelles, Samoa and the United States are USD, the functional currency of subsidiaries in Hong Kong is Hong Kong Dollars ("HKD"), the functional currency of a subsidiary in Singapore is Singapore Dollars ("SGD") and the functional currency of a subsidiary in the United Kingdom is Great British Pound ("GBP"). An entity's functional currency is the currency of the primary economic environment in which it operates, normally that is the currency of the environment in which it primarily generates and expends cash. The management considered various indicators, such as cash flows, market expenses, financing and inter-company transactions and arrangements in determining the Group's functional currency.

In the consolidated financial statements, the financial information of the Company and its subsidiaries, which use HKD, SGD and GBP as their functional currency, has been translated into USD. Assets and liabilities are translated from each subsidiary's functional currency at the exchange rates on the balance sheet dates, equity amounts are translated at historical exchange rates, and revenues, expenses, gains, and losses are translated using the average exchange rates for the year. Translation adjustments are reported as cumulative translation adjustments and are shown as a separate component of other comprehensive income or loss in the consolidated statements of operations and comprehensive income or loss.

Cash and cash equivalents

Cash and cash equivalents consists of cash on hand, bank deposits and time deposits with an original maturity of three months or less at the date of purchase.

Accounts receivable and amounts due from related parties

Accounts receivable and amounts due from related parties are stated at the original amount less an allowance for credit losses, if any, based on a review of all outstanding amounts at period end. An allowance is estimated in accordance with ASC Topic 326, *Credit Losses* and records the allowance for credit losses as an offset to accounts receivable or amounts due from related parties, and the expected credit losses charged to the allowance is included in other operating expenses in the consolidated statements of operations and comprehensive loss. In determining expected credit losses, the Group considers the historical level of credit losses, current economic trends, and reasonable and supportable forecasts that affect the collectability of the future cash flows. As of December 31, 2024 and 2023, $522,191 and $521,007 allowance for credit losses were made.

Inventories

Inventories are stated at lower of cost and net realizable value. Cost is determined using the weighted average method.

Where there is evidence that the utility of inventories, in their disposal in the ordinary course of business, will be less than cost, whether due to physical deterioration, obsolescence, changes in price levels, or other causes, the inventories are written down to net realizable value. During the years ended December 31, 2024, 2023 and 2022, the write-down of inventories were $nil, $13,206 and $nil respectively.

Long-term investments, net

The Group's long-term investments consist of equity method investment in common stocks and non-marketable investments in non-redeemable preferred shares of privately-held companies that are not required to be consolidated under the variable interest or voting models. Long-term investments are classified as non-current assets on the consolidated balance sheets as those investments do not have stated contractual maturity dates.

Non-marketable investments

The non-marketable equity securities not accounted for under the equity method are measured at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. Adjustments are determined primarily based on a market approach as of the transaction date. The Group also makes a qualitative assessment of whether the investment is impaired at each reporting date. If a qualitative assessment indicates that the investment is impaired, the Group has to estimate the investment's fair value in accordance with the principles of ASC 820. If the fair value is less than the investment's carrying value, the Group recognizes an impairment loss in earnings equal to the difference between the carrying value and fair value.

Equity method investment – Fair value option

The Group elects the fair value option for an investment that would otherwise be accounted for using the equity method of accounting. Such election is irrevocable and is applied on an investment by investment basis at initial recognition. The fair value of such investments is based on quoted prices in an active market, if any, or recent orderly transactions for identical or similar investment of the same issuer. Changes in the fair value of these equity method investments are recognized in other income (expenses), net in the consolidated statements of operations and comprehensive loss.

Fair value measurement

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Group considers the principal or most advantageous market in which it would transact its business, and it considers assumptions that market participants would use when pricing the asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy prioritizes the inputs utilized in measuring fair value as follows:

- Level 1 applies to assets or liabilities for which there are quoted prices in active markets for identical assets or liabilities.
- Level 2 applies to assets or liabilities for which there are inputs other than quoted prices included within Level 1 that are observable for the asset or liability such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical assets or liabilities in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.
- Level 3 applies to assets or liabilities for which there are unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

The hierarchy requires the Group to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Group has estimated the fair value amounts of its financial instruments using the available market information and valuation methodologies considered to be appropriate and has determined that the carrying value of the Group's cash, other receivables and prepayments, amounts due from/to related parties, accounts payable and accrued expenses, and convertible notes to a related party as of December 31, 2024 and 2023 approximate fair value due to the short-term nature of these assets and liabilities.

Property and equipment, net

Property and equipment, net, is stated at cost less accumulated depreciation and impairment losses. Cost represents the purchase price of the asset and other costs incurred to bring the asset into its existing use. Maintenance, repairs and betterments, including replacement of minor items, are charged to expense; major additions to physical properties are capitalized.

Assets under construction are stated at cost less impairment losses. Cost comprises of cost of laboratory equipment delivered but not ready to be used, together with interest expense capitalized during the period of construction or installation and testing. Capitalization of these costs ceases and the asset concerned is transferred to the appropriate fixed assets category when substantially all the activities necessary to prepare the asset for its intended use are completed.

Depreciation of property and equipment is provided using the straight-line method over their estimated useful lives:

Computer equipment	3 years
Furniture, fixture, and office and medical equipment	5 years
Leasehold improvements	Shorter of the remaining lease terms or 5 years
Laboratory equipment	5 years
Motor vehicle	5 years

Upon sale or disposal, the applicable amounts of asset cost and accumulated depreciation are removed from the accounts and the net amount less proceeds from disposal is charged or credited to operating expenses.

Intangible assets, net

Finite-lived intangible assets are carried at cost less accumulated amortization and impairment if any. The finite intangible assets are amortized over their estimated useful life, which is the period over which the assets are expected to contribute directly or indirectly to the future cash flows of the Group.

The Group's intangible assets mainly consist of computer software and is amortized over its useful life. The estimated useful life is generally 5 years. The Group will reassess the remaining useful life on annual basis.

Impairment of long-lived assets

The Group reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may no longer be recoverable. When these events occur, the Group compares the carrying value of the long-lived assets to the estimated undiscounted future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected undiscounted cash flow is less than the carrying amount of the assets, the Group would recognize an impairment loss, which is the excess of carrying amount over the fair value of the assets, using the expected future discounted cash flows.

Convertible notes

The Group evaluates and accounts for conversion options embedded in convertible notes in accordance with ASC 815 "Derivatives and Hedging Activities".

Applicable GAAP requires companies to bifurcate conversion options from their host instruments and account for them as derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under other GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Group accounts for the convertible notes as a single unit of account, unless the conversion feature requires bifurcation and recognition as derivatives. Additionally, the Group uses the if-converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of potential share settlement for instruments that may be settled in cash or shares.

Operating leases

At the inception of a contract, the Group determines if the arrangement is, or contains, a lease. Operating lease liabilities are recognized at lease commencement based on the present value of lease payments over the lease term. Operating lease right-of-use assets are initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred and less any lease incentives received. As the rate implicit in the lease cannot be readily determined, the Group uses incremental borrowing rate at the lease commencement date in determining the imputed interest and present value of lease payments. The incremental borrowing rate is determined based on the rate of interest that the Group would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term in a similar economic environment. The lease term for all of the Group's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Group's option to extend (or not to terminate) the lease that the Group is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor. For operating leases, the Group recognizes a single lease cost on a straight-line basis over the remaining lease term.

The Group has elected not to recognize right-of-use assets or lease liabilities for leases with an initial term of 12 months or less and the Group recognizes lease expense for these leases on a straight-line basis over the lease terms.

Warrants

In connection of the issuance of Class A Ordinary Shares, the Company may issue warrants to purchase Class A Ordinary Shares. Warrants classified as equity are initially recorded at fair value and subsequent changes in fair value are not recognized.

Revenue recognition

Revenues are derived from healthcare services rendered to patients for healthcare consultation and medical treatment. Revenue is reported at the amount that reflects the consideration to which the Group expects to be entitled in exchange for providing healthcare services.

The Group recognizes revenue as its performance obligations are completed. Healthcare services are treated as a single performance obligation satisfied at a point in time because the performance obligations are generally satisfied over a period of less than one day.

Cost of healthcare services

Cost of healthcare services rendered represents cost in relation to the medical services provided including the compensation of the physicians, cost of pharmaceutical supplies and medicine and write-down of inventories.

Research and development expenses

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including amortization of the patent license, depreciation of laboratory equipment, costs of engaging external consultants, advisors and contracted research organization to conduct preclinical development activities and trials, payroll expenses to research and development staff, sponsored research expenses to universities and research institutions, and impairment of patent license and laboratory equipment.

Government Subsidies

The Company's subsidiaries received government subsidies from certain local governments. The Company's government subsidies consisted of specific subsidies that are subsidies from the local government for a specific purpose, such as subsidies for research and development. The Company recorded specific subsidies as other income which is included in the consolidated statements of income upon receipt as further performance by the Company is not required. The government subsidies were approximately $0.9 million, $0.1 million and $0.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Share-based compensation

The Group uses the fair value method of accounting for the share options granted to directors, employees, external consultants and advisors to measure the cost services received in exchange for the share based awards. The fair value of share option awards with only service condition is estimated on the grant or offering date using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires inputs such as the risk-free interest rate, expected term and expected volatility. These inputs are subjective and generally require significant judgment. The resulting cost is recognized over the period during which a director, employee, external consultant or advisor is required to provide service in exchange for the awards, usually the vesting period, which is generally from 9.5 months to 21.5 months. Share-based compensation expense is recognized on a graded vesting basis, net of actual forfeitures in the period.

Share-based compensation expense is recorded in cost of healthcare services, research and development expenses, general and administrative fees and legal and professional fees in the consolidated statements of operations and comprehensive loss.

In accordance with ASC 718, modifications to stock-based awards are accounted for as exchanges of the original awards for new awards. The incremental fair value, which is the difference between the fair value of the modified award and the original award immediately before modification, is measured at the modification date. This incremental fair value is recognized immediately as compensation cost for vested awards. For unvested awards, the incremental compensation cost, along with any remaining unrecognized compensation cost of the original award, is recognized over the remaining requisite vesting period.

Income taxes

The Group accounts for income taxes under the asset and liability method. Under this method, deferred income taxes are determined based on differences between the financial carrying amounts of existing assets and liabilities and their tax bases. Income taxes are provided for in accordance with the laws of the relevant taxing authorities.

A valuation allowance is provided for deferred tax assets if it is more likely than not that these items will either expire before the Group is able to realize their benefits, or that future deductibility is uncertain. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

Uncertain tax positions

The Group accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. Interest and penalties related to uncertain tax positions are recognized and recorded as necessary in the provision for income taxes. The Group recognizes interest on non-payment of income taxes and penalties associated with tax positions when a tax position does not meet more likely than not thresholds be sustained under examination. The tax returns of the Group's Hong Kong subsidiaries are subject to examination by the relevant tax authorities. According to the Hong Kong Inland Revenue Department, the statute of limitation is six years if any company chargeable with tax has not been assessed or has been assessed at less than the proper amount, the statute of limitation is extended to ten years if the underpayment of taxes is due to fraud or willful evasion. According to United Kingdom, Singapore, the United States, Canada and Ireland tax rule, trading losses are available to be carried forward indefinitely. The Group did not have any material interest or penalties associated with tax positions for the years ended December 31, 2024, 2023 and 2022, and did not have any significant unrecognized uncertain tax positions as of December 31, 2024 and 2023. The Group does not believe that its assessment regarding unrecognized tax benefits will materially change over the next twelve months.

Comprehensive income or loss

Certain changes in assets and liabilities are reported as separate components of the equity section of the consolidated balance sheets, such items, along with net income or loss, are components of comprehensive income or loss. The components of other comprehensive income or loss consist of exchange differences on translation of foreign operations.

Net income or loss per share

Basic net income or loss per share is computed by dividing net income or loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted net income or loss per share reflects the potential dilution that could occur if securities or other contracts to issue ordinary shares were exercised or converted into ordinary shares. Potential dilutive securities are excluded from the calculation of diluted loss per share in loss periods as their effect would be anti-dilutive.

Segment reporting

The Group uses the management approach to determine operating segment. The management approach considers the internal organization and reporting used by the Group's chief operating decision maker (''CODM'') for making decisions, allocation of resource and assessing performance.

The Group operates and manages its business as a single operating and reportable segment. The Group's CODM has been identified as the Chief Executive Officer who reviews the consolidated net income (loss) when making decisions about allocating resources and assessing performance of the Group. Significant segment expenses are the same as these presented under the operating costs and expenses in the consolidated statements of operations, and the difference between net revenue less the significant segment expenses and consolidated net income are the other segment items. The CODM reviews and utilizes these financial metrics together with non-financial metrics to make operation decisions, such as the determination of the fee rate at which the Company charges for its services and the allocation of budget between operating costs and expense.

The Group's long-lived assets are substantially all located in Hong Kong and substantially all of the Group's revenues are derived from within Hong Kong. Therefore, no geographical segments are presented.

Concentration of credit risk

Financial assets which potentially subject the Group to concentrations of credit risk consist principally of bank deposits and balances.

The Group takes on exposure to credit risk on cash balances majority held with HSBC for the purposes of payments of Group expenses. The risk of default is considered minimal as the Group considers HSBC is well established with high credit rating.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures", which amends and enhances the disclosure requirements for reportable segments. All disclosure requirements under this standard will also be required for public entities with a single reportable segment. This new standard became effective for fiscal years beginning after December 15, 2023 and for interim periods within fiscal years beginning after December 15, 2024. The Group adopted this standard in the year ended December 31, 2024, which did not have a material impact on the consolidated financial statements and related disclosures.

Recently issued accounting standards which have not yet been adopted

In December 2023, the FASB issued Accounting Standards Update (ASU) 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances the transparency and decision usefulness of income tax disclosures. The amendments address more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The ASU also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in this ASU are effective for public business entities for annual periods beginning after December 15, 2024 on a prospective basis. Early adoption is permitted. The Group is still evaluating the effect of the adoption of this guidance.

ASU No. 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"), was issued in November 2024, which requires disclosure in the notes to the financial statements, of disaggregated information about certain costs and expenses that are included in expense line items on the face of the income statement. The requirements of ASU 2024-03 are effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027 with early adoption permitted. The Company is currently evaluating the impact, if any, that the adoption of this standard will have on its Consolidated Financial Statements and disclosures.

The Group does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material impact on the consolidated financial statements.

4. REVENUE

During the second quarter of 2023, the Group made a decision to streamline its operations by terminating clinic services and suspending non-lead R&D projects. No revenue was generated for the year ended December 31, 2024.

For the years ended December 31, 2023 and 2022, all revenue came from provision of healthcare services in Hong Kong.

5. INVESTMENT AND FAIR VALUE MEASUREMENT

Assets Measured at Fair Value on a Recurring Basis

The assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2024 and 2023 were $nil and $nil respectively.

For the year ended December 31, 2024, there was no movement in Level 3 assets measured and recorded at fair value on a recurring basis. The following is a reconciliation of Level 3 assets measured and recorded at fair value on a recurring basis during the years ended December 31, 2023.

	Common Stock
Balance at January 1, 2023	**$ 77,200**
Impairment	(77,200)
Balance at December 31, 2023	**$ -**

For the year ended December 31, 2023, an impairment loss relating to an equity method investment amounted to $77,200, was recorded in other expenses, net, as the Group considered that the carrying amount of the equity method investment may not be recoverable, and this condition is determined to be other-than-temporary.

Non-marketable investments

The Group's non-marketable investments are investments in privately held companies without readily determinable fair values. The carrying value of the non-marketable investments are adjusted based on price changes from observable transactions of identical or similar securities of the same issuer (referred to as the measurement alternative) or for impairment if the carrying amount of the non-marketable investments may not be fully recoverable. Any changes in carrying value are recorded within other income (expenses), net in the consolidated statements of operations and comprehensive loss.

The following is a summary of annual upward or downwards adjustments and impairment recorded in other income (expenses), net, and included as adjustments to the carrying value of non-marketable investments held as of December 31, 2024, 2023 and 2022 based on the observable price in an orderly transaction for the same or similar security of the same issuers:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Upward adjustments	$ -	$ 6,431,088	$ 6,108,872
Downward adjustments	-	-	-
Impairment	(1,000,000)	-	(520,821)
Total unrealized (loss) gain from fair value change of non-marketable investments, net	$ (1,000,000)	$ 6,431,088	$ 5,588,051

The Group did not sell any non-marketable investments or recorded any realized gains or losses for the non-marketable investments measured at fair value on a non-recurring basis during the years ended December 31, 2024, 2023 and 2022.

The Group recorded $1 million and $0.5 million impairment for the year ended December 31, 2024 and 2022 since the Group considered the investees' ability to continue as a going concern and the investment is not recoverable.

The following table summarizes the total carrying value of the non-marketable investments held as of December 31, 2024 and 2023 including cumulative unrealized upward and downward adjustments and impairment made to the initial cost basis of the investments:

	December 31, 2024	December 31, 2023
Initial cost basis	$ 4,079,707	$ 4,079,707
Upward adjustments	12,539,960	12,539,960
Downward adjustments	-	-
Impairment	(1,520,821)	(520,821)
Total carrying value at the end of the year	$ 15,098,846	$ 16,098,846

The Group did not transfer any non-marketable investments into marketable securities for the years ended December 31, 2024 and 2023.

For the years ended December 31, 2024 and 2023, one of the non-marketable investments with initial cost of $2.6 million and had $15.1 million carrying value was pledged for a convertible note issued to a related party (Note 15).

Equity method investment, fair value option

In December 2021, one of the Group's subsidiaries, Libra Sciences Limited ("Libra", formerly known as Aptorum Pharmaceutical Development Limited), issued Class A and Class B ordinary shares to various parties in exchange of licenses or cash. Each Class A share of Libra is entitled to 1 vote while each Class B share of Libra is entitled to 10 votes. Upon the share issuance, the Group was holding 97.27% economic interest and 31.51% voting power in Libra. The Group lost the controlling interest in Libra because it was transferred to a third party, and therefore deconsolidated Libra. However, the Group still owns 97.27% economic interest and 31.51% voting power, which is deemed as having significant influence over Libra. As a result, the Group's investment in Libra is subject to the equity method of accounting. The Group assessed that the fair value option can better reflect the true value of Libra. Pursuant to ASC 825 – Financial Instruments ("ASC 825"), the Group elected to apply the fair value option for its investments in Libra and will remeasure its investments in Libra at fair value every reporting period. For the year ended December 31, 2023, the Group has determined that the carrying value of the investment is not recoverable and this condition is determined to be other-than-temporary. Consequently, an impairment for the investment of nil and $77,200 has been recognized as of December 31, 2024 and 2023.

6. OTHER RECEIVABLES AND PREPAYMENTS

Other receivables and prepayments as of December 31, 2024 and 2023 consisted of:

	December 31, 2024	December 31, 2023
Prepaid research and development expenses	$ -	$ 185,633
Prepaid insurance	17,794	33,815
Prepaid service fee	50,538	46,303
Rental deposits	4,206	102,109
Prepaid rental expenses	-	15,683
Other receivables	4,545	22,275
Other deposits	8,233	16,253
	$ 85,316	$ 422,071

For the year ended December 31, 2024 and 2023, the Group considered certain other receivables and prepayments were not recoverable and recorded write-off of other receivables and prepayments of $45,677 and $62,369, respectively

7. PROPERTY AND EQUIPMENT, NET

Property and equipment as of December 31, 2024 and 2023 consisted of:

	December 31, 2024	December 31, 2023
Computer equipment	$ 69,291	$ 81,138
Furniture, fixture, and office and medical equipment	32,435	150,292
Leasehold improvements	108,187	543,975
Laboratory equipment	4,335,722	4,336,764
Motor vehicle	239,093	239,093
	4,784,728	5,351,262
Less: accumulated depreciation and impairment	4,784,728	3,687,336
Property and equipment, net	$ -	$ 1,663,926

Depreciation expenses for property, plant and equipment amounted to $235,827, $1,041,234 and $1,092,957 for the years ended December 31, 2024, 2023 and 2022, respectively.

For the year ended December 31, 2024, an impairment loss relating to laboratory equipment, computer equipment, and furniture, fixture, and office equipment amounted to $1,421,782 and $5,520 were recorded in research and development expenses and other operating expenses, respectively, as the Group considered that the carrying amount of these property and equipment may not be recoverable. For the year ended December 31, 2023, an impairment loss relating to the office and medical equipment, and computer equipment related to the Hong Kong healthcare services amounted to $28,128, was recorded in other operating expenses, as the Group considered that, with the termination of the healthcare services, the carrying amount of these property and equipment are not recoverable and are fully impaired. For the years ended December 31, 2022, no impairment loss was recorded.

For the year ended December 31, 2024, the Group recorded $58,621 gain on disposal of medical equipment in other operation expenses. For the year ended December 31, 2023, the Group recorded $79,822 of loss on disposal of laboratory equipment, and furniture, fixture, and office and medical equipment in other operating expenses. For the year ended December 31, 2022, no gain or loss on disposal was recorded.

8. INTANGIBLE ASSETS, NET

	December 31, 2024	December 31, 2023
Gross carrying amount		
Prepaid patented licenses	$ 200,000	$ 728,205
Computer software	223,858	223,858
	423,858	952,063
Less: accumulated amortization and impairment		
Prepaid patented licenses	200,000	728,205
Computer software	223,858	76,511
	423,858	804,716
Intangible assets, net		
Prepaid patented licenses	-	-
Computer software	-	147,347
Intangible assets, net	$ -	$ 147,347

As of December 31, 2022, the Group has capitalized eight of the exclusive licenses, which includes seven patented technologies. Pursuant to the license agreements, the Group paid upfront payments and became the exclusive licensee to prosecute certain patents developed or licensed under the applicable agreements.

For the year ended December 31, 2023, the Group terminated two of the licenses. For the year ended December 31, 2024, the Group terminated four of the licenses. The Group is in the process of terminating another license. The Group considered that the carrying amount of these intangible assets are not recoverable and are fully impaired. As a result, the Group recorded $519,496 impairment loss on intangible assets in research and development expenses for the year ended December 31, 2023. Besides, an impairment loss related to the computer software for Hong Kong healthcare services amounted to $128,128 was recorded in research and development expenses, and $1,841 was recorded in other operating expenses for the year ended December 31, 2024 and 2023, respectively.

For the year ended December 31, 2022, a loss on disposal of $205,189 related to a patented license was recognized in research and development expenses.

Prepaid patented licenses and computer software are finite-lived intangible assets which are amortized over their estimated useful life. Amortization expenses for finite-lived intangible assets amounted to $19,219, $84,020 and $114,553 for the years ended December 31, 2024, 2023 and 2022, respectively.

The Group does not expect any amortization expense related to its finite-lived intangible assets for the next five years and thereafter to be as follows as of December 31, 2024.

9. LONG-TERM DEPOSITS

Long-term deposits as of December 31, 2024 and 2023 consisted of:

	December 31, 2024	December 31, 2023
Rental deposits	$ 71,823	$ 71,823
	$ 71,823	$ 71,823

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of December 31, 2024 and 2023 consisted of:

	December 31, 2024	December 31, 2023
Deferred bonus and salaries payable	$ -	$ 451,660
Research and development expenses payable	778,205	1,162,155
Professional fees payable	127,031	175,324
Cost of healthcare services payable	-	61,826
Insurance expenses payable	-	27,463
Others	13,375	15,913
	$ 918,611	$ 1,894,341

On March 31, 2023, the Group entered into exchange agreements and cancelled 177,667 existing vested and unvested share options held by related parties option holders and cancelled its obligations for deferred cash bonus payables of $3.1 million by granting 403,820 share options with 6 months vesting period (see Note 17). The settlement of obligations of $3.1 million deferred cash bonus payables was deemed as capital contribution from related parties and was credited to additional paid-in capital.

On March 31, 2023, the Group entered into exchange agreements and cancelled 70,428 existing vested and unvested share options held by non-related parties option holders and cancelled its obligations for deferred cash bonus payables of $1.6 million by issuance of 70,430 fully vested Class A Ordinary Shares (see Note 16). The reversal of deferred cash bonus payables for $1.0 million and $0.6 million was credited to research and development expenses and general and administrative fees, respectively.

11. INCOME TAXES

The Company and its subsidiaries file tax returns separately.

Income taxes

Cayman Islands: under the current laws of the Cayman Islands, the Company and its subsidiaries in the Cayman Islands are not subject to taxes on their income and capital gains.

Hong Kong: in accordance with the relevant tax laws and regulations of Hong Kong, a company registered in Hong Kong is subject to income taxes within Hong Kong at the applicable tax rate on taxable income. In March 2018, the Hong Kong Government introduced a two-tiered profit tax rate regime by enacting the Inland Revenue (Amendment) (No.3) Ordinance 2018 (the “Ordinance”). Under the two-tiered profits tax rate regime, the first $2 million of assessable profits of qualifying corporations is taxed at 8.25% and the remaining assessable profits at 16.5%. The Ordinance is effective from the year of assessment 2018-2019. According to the policy, if no election has been made, the whole of the taxpaying entity’s assessable profits will be chargeable to Profits Tax at the rate of 16.5% or 15%, as applicable. Because the preferential tax treatment is not elected by the Group, all the subsidiaries registered in Hong Kong are subject to income tax at a rate of 16.5%. The subsidiaries registered in Hong Kong did not have assessable profits that were derived Hong Kong during the years ended December 31, 2024, 2023 and 2022. Therefore, no Hong Kong profit tax has been provided for in the periods presented. Our returns for 2018 and subsequent tax years remain subject to examination by Hong Kong Inland Revenue Department.

United Kingdom: in accordance with the relevant tax laws and regulations of United Kingdom, a company registered in the United Kingdom is subject to income taxes within United Kingdom at the applicable tax rate on taxable income. All the United Kingdom subsidiaries that are not entitled to any tax holiday were subject to income tax at a rate of 19%. The subsidiary in United Kingdom did not have assessable profits that were derived from United Kingdom during the years ended December 31, 2024, 2023 and 2022. Therefore, no United Kingdom profit tax has been provided for in the periods presented. Our returns for 2020 and subsequent tax years remain subject to examination by the UK tax authority.

Singapore: in accordance with the relevant tax laws and regulations of Singapore, a company registered in the Singapore is subject to income taxes within Singapore at the applicable tax rate on taxable income. All the Singapore subsidiaries that are not entitled to any tax holiday were subject to income tax at a rate of 17%. The subsidiary in Singapore did not have assessable profits that were derived from Singapore during the years ended December 31, 2024, 2023 and 2022. Therefore, no Singapore profit tax has been provided for in the periods presented. Our returns for 2020 and subsequent tax years remain subject to examination by the Singapore tax authority.

United States (Nevada): in accordance with the relevant tax laws and regulations of the United States, a company registered in the United States is subject to income taxes within the United States at the applicable tax rate on taxable income. All the United States subsidiaries in Nevada that are not entitled to any tax holiday were subject to income tax at a rate of 21%. The subsidiary in the United States did not have assessable profits that were derived from the United States during the years ended December 31, 2024, 2023 and 2022. Therefore, no United States profit tax has been provided for in the periods presented. Our returns for 2021 and subsequent tax years remain subject to examination by Internal Revenue Service.

The components of the provision for Income taxes expenses are:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Current	$ -	$ -	$ -
Deferred	-	-	-
Total income taxes expense	$ -	$ -	-

The reconciliation of income taxes expenses computed at the Hong Kong statutory tax rate applicable to income tax expense is as follows:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Net loss before tax	$ (4,157,737)	$ (4,340,975)	$ (11,525,102)
Provision for income tax benefit at Hong Kong statutory income tax rate (16.5%)	(686,027)	(716,261)	(1,901,642)
Impact of different tax rates in other jurisdictions	(10,814)	(16,272)	(263,787)
Non-taxable income	(5,477)	(1,071,774)	(907,495)
Non-deductible expenses	195	98,704	-
Change in valuation allowance	702,123	1,705,603	3,072,924
Effective income tax expense	$ -	$ -	$ -

Deferred tax asset, net

Deferred tax assets and deferred tax liabilities reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purpose and the tax bases used for income tax purpose. The following represents the tax effect of each major type of temporary difference.

	December 31, 2024	December 31, 2023
Deferred tax asset:		
Tax loss carry forward	$ 15,107,318	$ 16,956,748
Share-based payment expenses	-	229,126
Depreciation and amortization	128,896	128,866
Impairment loss on assets	537,830	92,416
Total Deferred tax asset	15,774,044	17,407,156
Valuation allowance	(15,774,044)	(17,407,156)
Deferred tax asset, net of valuation allowance	$ -	$ -

As of December 31, 2024 and 2023, the Group had net operating loss carry-forwards of $91,436,307 and $102,367,435, respectively, including its Hong Kong, Singapore, the United States, and the United Kingdom operations, which are available to reduce future taxable income and have an unlimited carryover period. For the year ended December 31, 2024, there was no tax loss carried forward expired, while tax loss brought forward of $13,854,614 was cancelled due to the disposal of various subsidiaries.

Valuation allowance was provided against deferred tax assets in entities where it was determined, it was more likely than not that the benefits of the deferred tax assets will not be realized. The Group had deferred tax assets which consisted of tax loss carry forward, which can be carried forward to offset future taxable income. The Group maintains a full valuation allowance on its net deferred tax assets. The management determines it is more likely than not that all of its deferred tax assets will not be utilized.

Changes in valuation allowance are as follows:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Balance as of January 1	$ 17,407,156	$ 15,705,088	$ 12,632,164
Additions	702,123	1,705,603	3,072,924
Disposal	(2,335,235)	(3,535)	-
Balance as of December 31	$ 15,774,044	$ 17,407,156	$ 15,705,088

12. RELATED PARTY BALANCES AND TRANSACTIONS

The following is a list of a director and related parties to which the Group has transactions with:

(a) Ian Huen, the Chief Executive Officer and Executive Director of the Group since November 2023. He was a Non-executive Director from June 2022 to November 2023. Before June 2022, he was the Chief Executive Officer and Executive Director;

(b) Jurchen Investment Corporation, the holding company and an entity controlled by Ian Huen;

(c) CGY Investment Limited, an entity owns more than 10% voting interest of the Group before April 2024;

(d) Aeneas Group Limited, an entity controlled by Ian Huen;

(e) Aenco Technologies Ltd, an entity being 34.56% effectively owned by Ian Huen;

(f) Aeneas Management Limited, an entity controlled by Ian Huen;

(g) Talem Medical Group Limited, an entity which Clark Cheng was a director;

(h) Libra Sciences Limited, an entity which was originally a wholly owned subsidiary of ATL. Since December 30, 2021, Libra has been turned into a related party to the Group due to the voting power owned by ATL is decreased to below 50% but more than 20%. (Note 13)

(i) ACC Medical Limited, an entity controlled by Clark Cheng, a former Executive Director of the Group before November 30, 2023

(j) Clark Cheng, a former Executive Director of the Group before November 30, 2023. After his resignation on November 30, 2023, he was no longer a related party of the Group.

(k) Darren Lui, a former Executive Director of the Group before November 27, 2023. After his resignation on November 27, 2023, he was no longer a related party of the Group.

Amounts due from related parties, net

Amounts due from related parties consisted of the following as of December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
Current		
Aeneas Management Limited	$ -	$ 961
Libra Sciences Limited (Note b)	522,192	521,007
Allowance for credit loss	(522,192)	(521,007)
Total	$ -	$ 961

Amounts due to related parties

Amounts due to related parties consisted of the following as of December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
Current		
Aeneas Group Limited (Note a)	$ 79,180	$ 79,180
Ian Huen	464	-
	$ 79,644	$ 79,180

	December 31, 2024	December 31, 2023
Convertible notes to a related party - Current		
Jurchen Investment Corporation (Note 15)	$ 3,238,500	$ -
Convertible notes to a related party - Non-current		
Jurchen Investment Corporation (Note 15)	$ -	$ 3,058,500

Related party transactions

Related party transactions consisted of the following for the years ended December 31, 2024, 2023 and 2022:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Loan from related parties (Note a)			
- Aeneas Group Limited	$ -	$ 2,500,000	$ 500,000
Issuance of Convertible Note to related parties (Note 15)			
- Jurchen Investment Corporation	$ -	$ 3,000,000	$ -
- Aenco Technologies Ltd	$ -	$ -	$ 3,000,000
Settlement of loan from a related party through issuance of Convertible Note (Note 15)			
- Aeneas Group Limited	$ -	$ 3,000,000	$ -
Interest expenses (Note a and Note 15)			
- Aeneas Group Limited	$ -	$ 71,123	$ 8,110
- Jurchen Investment Corporation	$ 180,000	$ 58,500	$ -
- Aenco Technologies Ltd	$ -	$ (13,234)	$ 13,234
Loan to related parties (Note b)			
- Libra Sciences Limited	$ -	$ 92,459	$ 330,341
Loan repayment and interest received from a related party (Note b)			
- Talem Medical Group Limited	$ -	$ 611,641	$ 2,962,153
Interest income (Note b)			
- Talem Medical Group Limited	$ -	$ 4,637	$ 164,600
- Libra Sciences Limited	$ -	$ 8,963	$ 14,232
Consultant, secondment, management and administrative services fees (Note c)			
- CGY Investments Limited	$ -	$ 153,640	$ 268,102
- ACC Medical Limited	$ -	$ 138,768	$ 209,626
Administrative management services (Note d)			
- Libra Sciences Limited	$ -	$ 9,615	$ 38,462
Healthcare services income			
- Aeneas Management Limited	$ -	$ 961	$ 1,282

Note a: On August 13, 2019, Aptorum Therapeutics Limited (“ATL”), a wholly owned subsidiary of the Company, entered into financing arrangements with Aeneas Group Limited, a related party, and Jurchen Investment Corporation, the ultimate parent of the Group, allowing ATL to access up to a total $15 million in line of credit debt financing. Both line of credits have originally matured on August 12, 2022. ATL and Aeneas Group Limited has mutually agreed to extend the line of credit arrangement further 3 years to August 12, 2025. The interest on the outstanding principal indebtedness is at the rate of 8% per annum. ATL may early repay, in whole or in part, the principal indebtedness and all interest accrued at any time prior to the maturity date without the prior written consent of the lender and without payment of any premium or penalty. As of the issuance date of this consolidated financial statements, the undrawn line of credit facility is $12 million.

Note b: On November 17, 2021, ATL entered into a loan agreement with Talem Medical Group Limited (the "Borrower"). According to the loan agreement, ATL granted a loan of up to AUD4,700,000 for the Borrower for general working capital purposes of the Borrower and its subsidiaries. The loan is interest-bearing at a rate of 10% per annum and secured by the entire issued shares of Talem Medical Group (Australia) Pty Limited held by the Borrower. The loan is initially matured 6 months from the date of the first drawdown. The maturity date was extended for 6 months to the first extended maturity date, and further extended for another 6 months to the second extended maturity date. As of the date of the issuance of this consolidated financial statements, there is no outstanding balance from the Borrower following a repayment in February 2023.

On January 13, 2022, ATL entered a line of credit facility with Libra Sciences Limited to provide up to a total $1 million line of credit for its daily operation. The line of credit is originally matured on January 12, 2023, and is extended for additional 3 years. The interest on the outstanding principal indebtedness is at the rate of 10% per annum. ATL and Libra Science Limited mutually agreed to terminate the line of credit agreement effect as of March 31, 2023. All existing liabilities arising from the line of credit agreement shall remain enforceable and repayable on demand by ATL. As of the issuance date of this consolidated financial statements, $0.5 million is outstanding from Libra Sciences Limited. For the year ended December 31, 2024 and 2023, the Group has assessed that the amounts due from Libra Science Limited and its subsidiary are potentially unrecoverable, and an allowance for credit loss amounting to $1,184 and $521,007 has been recognized, respectively.

Note c: CGY Investment Limited provided certain consultancy, advisory and management services to the Group on potential investment projects related to healthcare or R&D platforms. CGY Investment Limited is initially entitled to receive HK $104,000 (approximately $13,333) per calendar month plus reimbursement; such monthly service fee is adjusted to HK$171,200 (approximately US$21,949) with effect from March 1, 2022. In August 2023, CGY Investment Limited has agreed to suspended its monthly services fee from August 1, 2023. In November 2023, CGY Investment Limited and the Group reached a mutual agreement to terminate their contractual relationship.

ACC Medical Limited provided certain consultancy, advisory, and management services to the Group on clinic operations and other related projects for clinics' business development. ACC Medical Limited is initially entitled to receive HK $101,542 (approximately $13,018) per calendar month plus reimbursement; such monthly service fee is adjusted to HK$143,200 (approximately US$18,359 per month) effective from March 1, 2022. During the year ended December 31, 2023 and 2022, ACC Medical Limited also received $28,615 and $23,275 one-off compensation respectively. The agreement was terminated on June 30, 2023.

Note d: On January 1, 2022, Aptus Management Limited ("AML"), a wholly owned subsidiary of the Company, entered into an administrative management services agreement with Libra Sciences Limited. According to the agreement, AML will provide documentation and administrative services, include but are not limited to human resources and payroll administration, general secretarial and administrative support, and accounting and financial reporting services. AML is entitled to receive a fixed amount of services fees of HKD 25,000 (approximately $3,205) per calendar month with the original expiry date on December 31, 2023. AML and Libra Sciences Limited mutually agreed to terminate the administrative management service agreement effect as of March 31, 2023.

Note e: In accordance with mutual agreements reached with the board of directors, Mr. Clark Cheng and Mr. Ian Huen agreed to forgo their monthly remuneration effective July 1, 2023 until further notice. Moreover, Mr. Darren Lui consented to suspend his monthly remuneration from August 1, 2023 until further notice. Additionally, all independent non-executive directors consented to suspend their monthly remuneration from September 1, 2023 until further notice. Before the suspension of remuneration, Mr. Ian Huen, Mr. Clark Cheng, and Mr. Darren Lui had a monthly remuneration of $27,333, $6,410 and $6,667, respectively.

13. VARIABLE INTEREST ENTITY

The Company consolidates VIEs in which the Group has a variable interest and is determined to be the primary beneficiary. This determination is based on whether the Group has a variable interest (or combination of variable interests) that provides the Company with (a) the power to direct the activities that most significantly impact the VIE's economic performance and (b) the obligation to absorb losses or right to receive benefits that could be potentially significant to the VIE. The Group continually reassesses whether it is the primary beneficiary of a VIE throughout the entire period the Group is involved with the VIE.

On December 30, 2021, three of the Group's subsidiaries, Libra Sciences Limited ("Libra", formerly known as Aptorum Pharmaceutical Development Limited), Mios Pharmaceuticals Limited ("Mios") and Scipio Life Sciences Limited ("Scipio"), issued Class A and Class B ordinary shares to various parties; for each such entity, each Class A ordinary share is entitled to 1 vote and 1 share of economic benefit of the respective company, while each Class B ordinary share is entitled to 10 votes and 0.001 share of economic benefit of the respective company. Following such share issuances, the Group lost its majority voting rights in each of these three companies and only holds 48.33%, 48.39% and 48.36% economic interest in Libra, Mios and Scipio, respectively. However, the Group still holds a majority of each of these three company's outstanding Class A ordinary shares and therefore will absorb/receive portions of these subsidiaries' expected losses or residual returns. In addition, none of these three companies have sufficient equity to sustain its own activities, and they have two classes of ordinary shares which have different rights, benefits and obligations. We determined that all these three companies are variable interest entities ("VIE"). On December 31, 2021, Libra, Mios and Scipio further issued Class A ordinary shares to the Group in exchange of certain projects licenses. Upon these share issuances, the Group was holding 97.27% economic interest and 31.51% voting power in Libra, 97.93% economic interest and 36.17% voting power in Mios, and 97.93% economic interest and 35.06% voting power in Scipio, respectively.

We have considered each of these entity's Memorandum and Article of Association and their respective board of directors (the sole director of each of Mios and Scipio is an executive director of the Group), and determined that we have the power to manage and make decisions that affect Mios and Scipio's research and development activities, which activities most significantly impact Mios and Scipio's economic performance. However, we do not have such power over Libra's research and development activities, which activities most significantly impact Libra's economic performance. Accordingly, we determined that we are the primary beneficiary of Mios and Scipio, but not the primary beneficiary of Libra.

In November 2024, the Group acquired 10,000 Class A Ordinary Shares and 5,850,000 Class B Ordinary Shares of Scipio, achieving control over the entity. As a result of this acquisition, Scipio is no longer classified as a VIE under the Group and it became a subsidiary under the Group.

In October 2024, Mios was dissolved and ceased operation and it was deemed disposed by the Group.

The following tables summarize the aggregate carrying value of VIEs' assets and liabilities in the consolidated balance sheets that are consolidated:

	Assets	Liabilities	Net Assets
December 31, 2024			
Total	$ -	$ -	$ -
December 31, 2023			
Total	$ 24,352	$ 3,558	$ 20,794

As of December 31, 2024 and 2023, the aggregate carrying value of assets and liabilities in the Group's consolidated balance sheets that relate to the VIE in which the Group holds a variable interest but is not the primary beneficiary were $nil and $nil respectively.

The Group's maximum exposure to loss from its involvement with unconsolidated VIE represents the estimated loss that would be incurred if the VIE is liquidated, so that the fair value of the equity investment in VIE is zero and the amounts due from the VIE have to be fully impaired.

14. LEASE

As of December 31, 2024, the Group has a long-term operating lease for laboratories with remaining term expiring in 2026 and a remaining lease term of 1.2 years. Weighted average discount rates used in the calculation of the operating lease liability is 8%. The discount rates reflect the estimated incremental borrowing rate, which includes an assessment of the credit rating to determine the rate that the Group would have to pay to borrow, on a collateralized basis for a similar term, an amount equal to the lease payments in a similar economic environment.

	For the year ended December 31, 2024	For the year ended December 31, 2023
Lease cost		
Finance lease cost:		
Depreciation	$ -	$ -
Interest on lease liabilities	-	-
Operating lease cost	50,520	252,345
Short-term lease cost	3,374	65,221
Variable lease cost	-	-
Sublease income	-	-
Total lease cost	$ 53,894	$ 317,566
Other information		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 120,824	$ 389,365
Financing cash flows from finance leases	-	-
Right-of-use assets obtained in exchange for new operating lease liabilities	-	338,525
Weighted-average remaining lease term – finance leases	-	-
Weighted-average remaining lease term – operating leases	1.2 years	1.9 years
Weighted-average discount rate – finance leases	-%	-%
Weighted-average discount rate – operating leases	8.0%	8.0%

For the year ended December 31, 2024, an impairment loss of $144,051 on right-of-use assets was recognized in other operating expenses as the Group considered that the carrying amount of a right-of-use asset related to a lease of laboratory may not be recoverable.

For the year ended December 31, 2023, an impairment loss of $200,916 on right-of-use assets was recognized in other operating expenses as the Group considered that the carrying amount of a right-of-use asset related to a lease of clinic may not be recoverable. Additionally, the Group early terminated a lease agreement for a right-of-use asset relating to an office, which resulted in a recognized loss on early termination of the right-of-use asset totaling $31,030 in other operating expenses.

For the years ended December 31, 2022, the Group did not recognize any impairment losses and loss on disposal of right-of-use assets.

The maturity analysis of operating leases liabilities as of December 31, 2024 is as follows:

	December 31, 2024
Remaining periods ending December 31,	
2025	$ 97,541
2026	24,573
Total future undiscounted cash flow	122,114
Less: Discount on operating lease liabilities	(5,707)
Present value of operating lease liabilities	116,407
Less: Current portion of operating lease liabilities	(102,225)
Non-current portion of operating lease liabilities	$ 14,182

15. CONVERTIBLE NOTE

On December 9, 2022, the Group entered into a securities purchase agreement with Aenco Technologies Limited ("Aenco"). Pursuant to the securities purchase agreement, Aenco is purchasing a convertible note in the original principal amount of $3,000,000 (the "Dec 2022 Note"). The Dec 2022 Note is unsecured, convertible into the Company's restricted Class A Ordinary Shares at Aencco's option. The Dec 2022 Notes have a maturity date of 12 months subject to the Aenco's extension, a bullet interest rate of 7% per annum, and a conversion price of $12.00 per Class A Ordinary share. The Company shall have an obligation to repay the principal amount and interest of the Dec 2022 Note on the maturity date in cash or in unregistered Class A Ordinary Shares or a combination of such at the Company's discretion. In April 2023, Aenco transferred the whole Dec 2022 Note to two external investors, and the two external investors fully converted the Dec 2022 Note into 250,000 Class A Ordinary Shares.

On June 28, 2023, the Group entered into a securities purchase agreement with 4 investors. Pursuant to the securities purchase agreement, the investors are purchasing a convertible note in the original principal amount of $3,000,000 (the "June 2023 Note"). The whole proceeds from the June 2023 Note was used to settle a related party loan. The June 2023 Note is unsecured, convertible into the Company's restricted Class A Ordinary Shares at the Note holders' option. The June 2023 Notes have a maturity date of 12 months subject to the investors extension, a bullet interest rate of 7% per annum, and a conversion price of $3.00 per Class A Ordinary share. The Company shall have an obligation to repay the principal amount and interest of the June 2023 Note on the maturity date in cash or in unregistered Class A Ordinary Shares or a combination of such at the Company's discretion. Immediately following the issuance of June 2023 Note, the June 2023 Note was fully converted into 1,000,000 Class A Ordinary Shares.

On September 11, 2023, the Group entered into a securities purchase agreement with Jurchen Investment Corporation, the largest shareholder of the Company, pursuant to which the Group sold a secured convertible note in the aggregate principal amount of $3,000,000 (the "Sep 2023 Notes"). The Sep 2023 Notes are convertible into the Company's Class A Ordinary Shares and have a maturity date that is 24 months from the issuance date, although upon such date the investor has the right to extend the term of the Sep 2023 Note for twelve (12) months or more or such term subject to mutual consent. The Sep 2023 Notes have an interest rate of 6% per annum and a conversion price of $2.42 per share. The Company has the right to repay the principal amount of the Sep 2023 Notes, but in the case of such prepayment it must be paid in cash, unless otherwise agreed by both parties. The Sep 2023 Note is secured by a first priority lien and security interest on certain preferred shares that the Group owns ("Collateral") (Note 5). Upon the Group's disposal of all or a portion of the Collateral, the investor has the right, to request that the Group prepay the then-remaining outstanding balance of the Sep 2023 Note, in part or in full and the Group can make that payment in cash or in shares.

16. ORDINARY SHARES

On March 26, 2021, the Company entered into an at-the-market offering agreement (the "Sales Agreement"), with H.C. Wainwright & Co., LLC, acting as its sales agent (the "Sales Agent"), relating to the sale of its Class A Ordinary Shares (such offering, the "ATM Offering", or "At The Market Offering"). In accordance with the terms of the Sales Agreement, the Company may offer and sell shares of its Class A Ordinary Shares having an aggregate offering price of up to $15,000,000 from time to time through the Sales Agent under such prospectus supplement and the accompanying prospectus. For the year ended December 31, 2023, the Company has issued 215,959 Class A Ordinary Shares at average issuance price of $7.53 per share pursuant to the ATM Offering with gross proceeds of $1.6 million, less transaction costs of $50,183.

On January 23, 2023, the Company effectuate a 10 for 1 share consolidation of its authorized share capital, such that every 10 Class A Ordinary Shares, par value of US$1.00 per share, in the authorized share capital of the Company (including issued and unissued share capital) were consolidated into 1 Class A Ordinary Share, par value of US$10.00 per share, and that every 10 Class B Ordinary Shares, par value of US$1.00 per share in the authorized share capital of the Company (including issued and unissued share capital) were consolidated into 1 Class B Ordinary Share, par value of US$10.00 per share. As a consequence of the reverse stock split, fractional shares were rounded up to the next whole share, resulting in the creation of an additional 8,018 Class A Ordinary Shares.

On February 21, 2023, the Company was merged with Aptorum Group Cayman Limited, a newly established wholly owned subsidiary of the Company, whereby the Company is the surviving company on the terms of the plan of merger. According to the plan of merger, the par value of its Class A and Class B Ordinary Shares are changed from USD10 to USD0.00001.

On March 31, 2023, the Group issued 70,430 Class A Ordinary Shares to a majority of the share option holders. This issuance served as an exchange for their share options and facilitated the reversal of deferred cash bonus payables owed to these holders (See Note 10).

On March 31, 2023, the Group also issued 65,770 fully vested Class A Ordinary Shares to certain employees and external consultants. The grant date fair value of each of the shares was $2.68 based on grant date quoted market price.

For the years ended December 31, 2024, 2023 and 2022, the Group issued 427,060, 791 and 6,712 Class A Ordinary Shares to share option holders as a result of exercise of options, respectively.

For the year ended December 31, 2024, the Group issued 446,842 Class A Ordinary Shares to Class B Ordinary Shares holders upon conversion.

For the year ended December 31, 2023, the Group issued 1,250,000 Class A Ordinary Shares to convertible note holders upon conversion (See Note 15).

Holders of Class A Ordinary Shares and Class B Ordinary Shares have the same rights except for the following: (i) each Class A Ordinary Share is entitled to one vote while each Class B Ordinary Share is entitled to ten votes; and (ii) each Class B Ordinary Share is convertible into one Class A Ordinary Share at any time while Class A Ordinary Shares are not convertible under any circumstances.

17. SHARE BASED COMPENSATION

Share option plan

On October 13, 2017, the Group adopted the 2017 Share Option Plan (the “Option Plan”) and on November 5, 2021, the Group amended the Option Plan. A total of 550,000 Class A Ordinary Shares (subject to subsequent adjustments described more fully below) may be issued pursuant to awards under the Option Plan. Subsequent adjustments include that on each January 1, starting with January 1, 2020, an additional number of shares equal to the lesser of (i) 2% of the outstanding number of Class A Ordinary Shares (on a fully diluted basis) on the immediate preceding December 31, and (ii) such lower number of Class A Ordinary Shares as may be determined by the board of directors, subject in all cases to adjustments as provided in Section 10 of the Option Plan. Awards will be made pursuant to agreements and may be subject to vesting and other restrictions as determined by the board of directors.

153,146 options were granted on March 8, 2022 to directors, employees, external consultants and advisors of the Group with an exercise price of $13.4 per share, which was based on the average closing price of the shares traded on the NASDAQ stock exchange for the five trading days immediately preceding the grant date. 74,881 options vest on January 1, 2023 and expire on December 31, 2033; 74,906 options vest on January 1, 2024 and expire on December 31, 2034; 1,866 options vest on June 8, 2022 and expire on June 7, 2033; and 1,493 options vest on July 14, 2022 and expire on July 13, 2033.

On March 31, 2023, the Group entered into exchange agreements and cancelled 177,667 existing vested and unvested share options held by related parties option holders and cancelled the Group’s obligations for deferred cash bonus payables of $3.1 million by granting of 403,820 share options (“New Options”) with 6 months vesting period. The New Options’ exercise price was $2.68 per share, which was based on the last closing price of the shares traded on the NASDAQ stock exchange on the grant date. All options fully vested on October 1, 2023 and expires on September 30, 2033. On March 31, 2023, the Group entered into supplemental agreements with the same related parties option holders to provide additional cash compensation to cover the exercise price of the New Options. On March 31, 2023, the Group entered into exchange agreements and cancelled 70,428 existing vested and unvested share options held by non-related parties option holders and cancelled the Group’s obligations for deferred cash bonus payables of $1.6 million by issuance of 70,430 fully vested Class A Ordinary Shares. The Group accounted for this exchange for both related parties and non-related parties share option holders as a modification to share based compensation which required the remeasurement of existing share options value at the time of the modification. The total incremental cost as a result of the modification was $0.7 million.

A summary of the option activity for the years ended December 31, 2024, 2023 and 2022 and changes during the period is presented below:

	Number of share options	Weighted average exercise price $	Remaining contractual term in years	Aggregate Intrinsic value
Outstanding, January 1, 2024	427,060	3.59	9.28	
Exercised	(427,060)	1.49		1,436,963
Outstanding, December 31, 2024	-	-	-	-
Exercisable, December 31, 2024	-	-	-	-

	Number of share options	Weighted average exercise price $	Remaining contractual term in years	Aggregate Intrinsic value
Outstanding, January 1, 2023	272,126	21.54	10.83	
Granted	403,820	2.68		
Exercised	(791)	20.90		-
Modified	(248,095)	21.74		
Outstanding, December 31, 2023	427,060	3.59	9.28	-
Exercisable, December 31, 2023	420,157	3.43	9.42	-

	Number of share options[1]	Weighted average exercise price $	Remaining contractual term in years	Aggregate Intrinsic value
Outstanding, January 1, 2022	127,404	31.91	11.01	
Granted	153,146	13.40	12.30	
Exercised	(6,721)	25.25		-
Forfeited	(1,268)	28.11		
Cancelled	(435)	116.71		
Outstanding, December 31, 2022	272,126	21.54	10.83	-
Exercisable, December 31, 2022	89,300	32.71	9.64	-

(1) All per share amounts and shares outstanding for all periods have been retroactively restated to reflect APTORUM GROUP LIMITED's 1 for 10 reverse stock split, which was effective on January 23, 2023.

The weighted-average grant date fair value of share option grants during the years ended December 31, 2023 and 2022 was $2.68 and $10.02, respectively. The maximum contractual term for share option was 12.8 years.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model under the following assumptions.

	Granted in 2023	Granted in 2022
Expected volatility	170.10%	89.55%
Risk-free interest rate	3.48%	1.86%
Expected term from grant date (in years)	5.25	5.63-6.41
Dividend rate	-	-
Dilution factor	1	1
Fair value	$ 2.68	$ 9.74 - $10.16

In connection with the grant of share options to employees and non-employees, the Group recorded share-based compensation charges of $697,446 and $391,479, respectively, for the year ended December 31, 2023, and $1,123,122 and $523,877, respectively, for the year ended December 31, 2022. For the year ended December 31, 2024, there were no charges related to share-based compensation.

18. NON-CONTROLLING INTEREST

On February 25, 2022, Aptorum Medical Limited issued 119 shares to Clark Cheng in according to the appointment agreement, decreasing the equity interest of the Company from 92% to 91%. On February 1, 2023, Aptorum Medical Limited further issued 122 shares to Clark Cheng in according to the appointment agreement, decreasing the equity interest of the Company from 91% to 90%. As a result, a total deficit of $67,766 and $52,024, were reclassified from additional paid-in capital to non-controlling interests within the Group's consolidated financial statements for the years ended December 31, 2023 and 2022, respectively.

In November 2024, the Group acquired 10,000 Class A Ordinary Shares and 5,850,000 Class B Ordinary Shares of Scipio, achieving control over the entity. As a result of this acquisition, Scipio is no longer classified as a VIE under the Group and it became a subsidiary under the Group.

19. NET LOSS PER SHARE

The following table sets forth the computation of basic and diluted loss per share:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Numerator:			
Net loss attributable to Aptorum Group Limited	$ (4,267,806)	$ (2,824,647)	$ (9,799,560)
Denominator:			
Weighted average shares outstanding[(1)]			
–Basic[(1)]	5,453,103	4,521,133	3,569,484
–Diluted[(1)]	5,453,103	4,521,133	3,569,484
Net loss per share attributable to Aptorum Group Limited[(1)]			
–Basic[(1)]	$ (0.78)	$ (0.62)	$ (2.75)
–Diluted[(1)]	$ (0.78)	$ (0.62)	$ (2.75)

(1) All per share amounts and shares outstanding for all periods have been retroactively restated to reflect APTORUM GROUP LIMITED's 1 for 10 reverse stock split, which was effective on January 23, 2023.

For the years ended December 31, 2024, 2023 and 2022, the total number of share options, warrants and convertible notes excluded from the calculation of diluted earnings per share due to their anti-dilutive nature, are 1,392,277, 1,293,723 and 54,054, respectively.

20. COMMITMENTS AND CONTINGENCIES

Contingent Payment Obligations

As of December 31, 2024, the Group does not have any non-cancellable purchase commitments.

The Group has contingency payment obligations under each of the license agreements, such as milestone payments, royalties, research and development funding, if certain condition or milestone is met.

Milestone payments are due upon achievements of specific conditions, such as Investigational New Drugs ("IND") filing or U.S. Food and Drug Administration ("FDA") approval, first commercial sale of the licensed products, or other achievements. The aggregate amounts of the contingent milestone payments that the Group is required to pay up to different achievements of conditions and milestones under all license agreements in effect as of December 31, 2024 are below:

	Amount
Drug molecules: up to the conditions and milestones of	
Preclinical to IND filing	$ 30,000
From entering phase 1 to before first commercial sale	2,120,000
First commercial sale	1,600,000
Net sales amount more than certain threshold in a year	14,000,000
Subtotal	$ 17,750,000
Diagnostics technology: up to the conditions and milestones of	
Before FDA approval	$ 146,417
	$ 17,896,417

For the years ended December 31, 2024, 2023 and 2022, the Group incurred $61,123, $50,000 and $nil milestone payments under license agreements, respectively. For the years ended December 31, 2024, 2023 and 2022, the Group did not incur any royalties or research and development funding, respectively.

Legal proceedings

On December 16, 2024, the Group received a letter from Carey Olsen with a Summons with Notice dated September 3, 2024, taken out by Karen Cheung (a/k/a Wing TSZ Cheung) as plaintiff against, among others, the Group as defendant in the Supreme Court of the State of New York County of New York, in relation to an action to recover financial losses sustained by the plaintiff (the "Case"). The Case is at the very early stages of litigation and although we intend to defend the lawsuit, there can be no assurance regarding the ultimate outcome of this case.

From time to time, the Group may be subject to certain legal proceedings, claims and disputes that arise in the ordinary course of business. Although the outcomes of these legal proceedings cannot be predicted, the Group does not believe these actions, in the aggregate, will have a material adverse impact on its financial position, results of income or liquidity.

21. SUBSEQUENT EVENTS

The Group evaluates all events and transactions that occur after December 31, 2024, other than the event disclosed below and elsewhere in these consolidated financial statements, there is no other subsequent event occurred that would require recognition or disclosure in the Group's consolidated financial statements.

On January 2, 2025, the Company entered into a certain securities purchase agreement (the "Securities Purchase Agreement") with certain non-affiliated institutional investors (the "Purchasers") pursuant to which the Company sold 1,535,000 Class A ordinary shares of the Company (the "Shares"), par value $0.00001 per share (the "Ordinary Shares") at a per share price of $2.00 in a registered direct offering, for gross proceeds of $3,070,000 (the "Offering"). The Securities Purchase Agreement was fully executed on January 3, 2025.

Exhibit 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

I, Ian Huen, certify that:

1. I have reviewed this annual report on Form 20-F of Aptorum Group Limited;

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: April 30, 2025

/s/ Ian Huen

Name: Ian Huen
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Wong Kwok Kuen, certify that:

1. I have reviewed this annual report on Form 20-F of Aptorum Group Limited;

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: April 30, 2025

/s/ Wong Kwok Kuen

Name: Wong Kwok Kuen
Title: Head of Finance
(*Principal Financial Officer*)

Exhibit 13.1

Certifications Pursuant to 18 U.S.C. Section 1350

Pursuant to U.S.C. Section 1350 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), the undersigned officers of Aptorum Group Limited (the "Company"), do hereby certify, to such officer's knowledge, that:

The Annual Report on Form 20-F for the year ended December 31, 2024, of the Company fully complies, in all material respects, with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 20-F fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 30, 2025

/s/ Ian Huen

Ian Huen
Chief Executive Officer
(Principal Executive Officer)

/s/ Wong Kwok Kuen

Wong Kwok Kuen
Head of Finance
(Principal Financial Officer)

Exhibit 15.1

MARCUMASIA

Independent Registered Public Accounting Firm's Consent

We consent to the incorporation by reference in the Registration Statement on Form F-3 (FILE NO. 333-268873) and Form S-8 (FILE NO. 333-281028) of our report dated April 30, 2025 relating to the consolidated financial statements of Aptorum Group Limited appearing in this Annual Report on Form 20-F for the year ended December 31, 2024.

/s/ Marcum Asia CPAs LLP

Marcum Asia CPAs LLP
New York, NY
April 30, 2025