

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

Pre-Effective Amendment 2
to
FORM S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Niki BioSolutions, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

42-3265309
I.R.S. Employer Identification Number

116 Village Boulevard, Suite 200
Princeton, NJ 08540
Tel: 609-951-2222
(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

Ian Huen
Chief Executive Officer
116 Village Boulevard, Suite 200
Princeton, NJ 08540
Tel: 609-951-2222
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Louis Taubman, Esq.
Hunter Taubman Fischer & Li LLC
950 Third Avenue, 19th Floor
New York, NY 10022
(212) 530-2206

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

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

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

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

EXPLANATORY NOTE

Niki BioSolutions, Inc. (the “Registrant”) is filing this Pre-Effective Amendment No. 2 to the Registration Statement on Form S-3, originally filed on August 28, 2026 to update disclosure based on comments received from the US Securities and Exchange Commission relating to not being able to incorporate foreign forms by reference since we are now a domestic entity and to include additional disclosure regarding the legal and operational risks associated with having a significant portion of our business in Hong Kong.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement relating to these securities that has been filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

(Subject to Completion, dated [])

PRELIMINARY PROSPECTUS

\$75,000,000
Niki BioSolutions, Inc.
Common Stock
Preferred Stock
Warrants
Subscription Rights
Debt Securities
Units

We may from time to time, in one or more offerings at prices and on terms that we will determine at the time of each offering, sell Common Stock, preferred stock, warrants, subscription rights, debt securities, units, or a combination of these securities, for an aggregate offering price of up to \$75,000,000. This prospectus describes the general manner in which our securities may be offered using this prospectus. Each time we offer and sell securities, we will provide you with a prospectus supplement that will contain specific information about the terms of that offering. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement.

Our Common Stock, par value \$0.0001 per share (the “Common Stock”), is currently listed on the Nasdaq Capital Market under the symbol “NIKI”. As of the date of this prospectus, none of the other securities that we may offer by this prospectus is listed on any national securities exchange or automated quotation system.

As of September 16, 2026, the aggregate market value of our Common Stock held by non-affiliates was \$5,040,597.33 based on 1,056,729 shares of outstanding Common Stock held by non-affiliates and the closing price of \$4.77 on September 16, 2026.

Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our securities in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75,000,000. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

We are a holding company incorporated in the State of Delaware with no material operations of our own, other than through our wholly owned subsidiary DiamiR Biosciences, Corp., a Delaware corporation (“DiamiR”). Through our direct and indirectly wholly owned subsidiaries, we conduct a significant portion of our operations in Hong Kong. The holding company structure is not used to provide investors with exposure to foreign investment in China-based companies where Chinese law prohibits direct foreign investment in such operating companies. None of our subsidiaries is subject to any prohibitions or restrictions on direct foreign investment under Chinese laws. The holding company structure involves unique risks to the investors, and Chinese regulatory authorities could disallow this structure, which would likely result in a material change in our operations and/or a material change in the value of our securities, including that such event could cause the value of such securities to significantly decline or become worthless. Investing in our common stock involves a high degree of risk, including the risk of losing your entire investment. We do not own substantial assets or conduct substantial operations in the People’s Republic of China (the “PRC”), but our principal business operations are conducted in Hong Kong and therefore we are considered a China-based issuer and are currently subject to PRC regulation and oversight, which may have a material adverse effect on our business operations and the value of our securities. 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, which may result in a material change in our operations and/or the value of our common stock, which would materially affect the interest of the investors. The governing laws and regulations of the PRC are still rapidly evolving and subject to changes. Further, the Chinese government may be authorized by PRC laws to regulate PRC and Hong Kong operating entities at any time and may regulate the offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in the operations of PRC operating entities and/or the value of their securities. In addition, any actions by the Chinese government to regulate the offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

For risks applicable to the Company regarding operations in Hong Kong, see “*Risk Factors*” beginning on page 2 of this prospectus.

We are aware that in recent years, the Chinese government initiated a series of regulatory actions and statements to regulate business operations in China with little advance notice, including cracking down on illegal activities in the securities market, enhancing supervision over China-based companies listed overseas adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement, which may impact our ability to conduct our business, accept foreign investments or list on a U.S. or other foreign exchange. Furthermore, pursuant to the Basic Law of the Hong Kong Special Administrative Region of the People's Republic of China ("Basic Law"), national laws of mainland China 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 the anti-monopoly have not been listed in Annex III, so they do not apply directly to Hong Kong entities. However, due to the long-arm application of the current PRC laws and regulations, the PRC government may exercise significant direct oversight and discretion over the conduct of our business and may intervene or influence our operations at any time, which could result in a material change in our operations and/or the value of our common stock. There remains regulatory uncertainty with respect to the implementation and interpretation of laws in China. We are also subject to the risks of uncertainty about any future actions of the PRC government or authorities in Hong Kong in this regard. Nevertheless, since these statements and regulatory actions made by the PRC government are relatively recent, 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. The application of PRC 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 common stock, to significantly decline or become worthless.

As of the date of this prospectus, we are also aware that the China Security Regulatory Commission, or CSRC, promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines thereto, which came into effect on March 31, 2023 and request that the domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete filing procedures with the CSRC within three working days following its submission of confidential or public registration statement for initial public offerings or listing. 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 Libra, however, your investments are into the Delaware holding company, not Libra, and you may never own any equity in Libra or any other subsidiary. Therefore, we do not believe that we are required to obtain approval or clearance from the CSRC as the listing of our common stock on Nasdaq does not constitute an "indirect overseas offering and listing by PRC domestic companies" nor that we are required to complete the filing procedures as stipulated by the Trial Measures because the Company's majority business activities are neither carried out in Mainland China, nor is its main place of business located in Mainland China. However, if our assessment that we are not required to complete the filing procedures as stipulated by the Trial Measures is incorrect, and if the Trial Measures do eventually apply to us, we cannot assure you that we will be able to receive the clearance of filing procedures under the Trial Measures on a timely basis, or at all. Any failure by us to fully comply with new regulatory requirements, including but limited to the failure to complete the filing procedures with the CSRC if required, may significantly limit or completely hinder our ability to offer or continue to offer our common stock, cause significant disruption to our business operations, and severely damage our reputation, which would materially and adversely affect our financial condition and results of operations and cause our common stock to significantly decline in value or become worthless. For a detailed description of the risks related to doing business in the PRC, and the offering, see "Risk Factors — Risks Related to Our Corporate Structure" and "Risk Factors — Risks Relating to Doing Business in Hong Kong".

Based on a thorough review of applicable laws and regulations, we have concluded that other than our business registration from Inland Revenue Department for tax registration, we do not need any permissions or approvals to operate our business and we affirmatively state that we have received all requisite permissions or approvals necessary to operate our business, and can affirmatively state that no related permissions or approvals have been denied. Neither we nor our subsidiaries are required to obtain permissions or approvals from the China Securities Regulatory Commission (CSRC), the Cyberspace Administration of China (CAC), or any other PRC governmental authority to operate our business or offer securities to foreign investors. We affirmatively state that we have received all requisite permissions or approvals necessary to operate our business, and no permissions or approvals have been denied. However, regulatory requirements on cybersecurity and data security in the mainland China are constantly evolving and can be subject to varying interpretations or significant changes, which may result in uncertainties about the scope of our responsibilities in that regard, and there can be no assurance that the relevant PRC governmental authorities, including the CAC, would reach the same conclusion as us. We will closely monitor and assess the implementation and enforcement of the Cybersecurity Review Measures. If the Cybersecurity Review Measures mandates clearance of cybersecurity and/or data security regulators and other specific actions to be completed by companies like us, we may face uncertainties as to whether we can meet such requirements timely, or at all.

Regarding the cash transfer throughout our organization, our management is directly supervising cash management. Cash is generally transferred through our organization as follows: the parent company may provide funding to its subsidiaries through capital contributions or intercompany loans, and subsidiaries may transfer cash to the parent company in the form of dividends or other distributions, subject to applicable laws and regulations.

Up through September 16, 2026, we have transferred the noted amount to the referenced subsidiary:

Subsidiaries	US\$
Aptus Management Ltd	64,309,272.68
Aptorum Medical Ltd ¹	1,673,592.92
Aptorum Therapeutics Ltd	17,635,261.58
Acticule Life Sciences Ltd	5,218,255.31
Aptorum Innovations Holding Ltd	15,087.11
Aptorum Innovations Holding Pte	442,201.61
Aptorum Group LLC	4,337.75
Claves Life Sciences Ltd ¹	331,959.92
Scipio Life Sciences Ltd	151,710.07
Signate Life Sciences Ltd ¹	319,385.76
Aptorum Pharmaceutical Dev. Ltd	7,300.00

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 us. 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. Currently, there are no restrictions or limitations imposed by any governmental authority in the jurisdictions where we operate, including the People's Republic of China, on the ability of our subsidiaries to transfer cash to the parent company or vice versa. We affirm that we have not experienced any difficulties or delays in transferring cash within our organization. However, if applicable laws, regulations, or interpretations change in the future, or if we inadvertently fail to comply with such requirements, we may face restrictions on transferring funds, which could adversely affect our ability to fund operations, meet financial obligations, or pay dividends to shareholders.

We have implemented cash management policies for all of our subsidiaries, which require the relevant financial staff to verify that the relevant documents issued by the requesting staff with the approval of the competent supervisor are qualified, and then transfer the payment to the cashier upon competent supervisor of the relevant financial staff. Any voucher will be stamped after payment and the payee will sign the request for payment as receipt. In addition, all payments shall be made by remittance, crossed and stamped non-endorsed transfer cheques except for certain specified cash payables. When transferring any inter-group funds, the cash management procedures are the same as the cash management policies for external payment as set out above.

Our group intends to retain all available funds and future earnings, if any, for the operation and expansion of our business and does not anticipate declaring or paying any dividends in the foreseeable future. We also intend to settle amounts owned under our operating structure through bank loans and loans from related parties. We currently do not have any dividend policy, and any future determination will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. As of the date of this prospectus, neither we nor any of our subsidiaries have ever paid dividends or made distributions to U.S. investors any return on investment may be limited to the value of our common stock. We plan to retain any future earnings to finance growth. Save as disclosed, there were no other transfers, dividends or distributions which have been made between our holding company, our subsidiaries or to our investors. If we determine to pay dividends on any of our common stock in the future, as a holding company, we will be dependent on receipt of funds from our operating subsidiaries in Hong Kong. If Libra or subsidiaries incur debt on their own behalf in the future, the instruments governing such debt may restrict their ability to pay dividends to us. To date, there have not been any such dividends or other distributions from Libra or subsidiaries to our subsidiaries located outside of China. In addition, as of the date of this prospectus, neither Libra nor any of our subsidiaries nor investments have ever issued any dividends or distributions to us or their respective shareholders outside of China.

¹ This entity has been struck off the Cayman Islands' registry and dissolved.

Pursuant to the Holding Foreign Companies Accountable Act (the “HFCAA”), the Public Company Accounting Oversight Board (the “PCAOB”) issued a Determination Report on December 16, 2021 which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in:

(1) mainland China of the PRC, and (2) Hong Kong, because of positions taken by the PRC authorities in those jurisdictions. In addition, the PCAOB’s report identified the specific registered public accounting firms which are subject to these determinations. Our current independent accounting firm, Marcum Asia CPAs LLP, whose audit report is included herein, is headquartered in Manhattan, New York, with an address of 7 Penn Plaza, Suite 830, New York, New York 10001. Our auditors have been inspected by the PCAOB on a regular basis. Therefore, our auditors were not identified in this report as a firm subject to the PCAOB’s determination. On August 26, 2022, the CSRC, the Ministry of Finance of the PRC, and the PCAOB signed a Statement of Protocol, or the Protocol, governing inspections and investigations of audit firms based in China and Hong Kong. Pursuant to the Protocol, 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. 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 uncertainty and depends on a number of factors out of our control. 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 in 2022, and the PCAOB Board vacated its previous 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 uncertainty and depends on a number of factors out of our control. The PCAOB continues to demand complete access in mainland China and Hong Kong moving forward and has resumed regular inspections since March 2023. The PCAOB is continuing pursuing ongoing investigations and may initiate new investigations as needed. The PCAOB has indicated that it will act immediately to consider the need to issue new determinations with the HFCAA if needed. As such, trading in our securities may be prohibited under the HFCAA if we appoint an auditor that the PCAOB determines that it cannot inspect or investigate completely, and as a result our securities may be delisted. On December 23, 2022, the Accelerating Holding Foreign Companies Accountable Act (“AHFCAA”) was enacted, which 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. On December 29, 2022, a 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 AHFCAA 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 before a Company’s securities may be prohibited from trading or delisted. See *“Risk Factors — 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 common stock. A trading prohibition for our common stock, 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.”* and *“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.”* for more information.

The interpretation and enforcement of PRC laws and regulations could limit the legal protection available to you and us, hinder our ability to offer or continue to offer the common stock, result in a material adverse effect on our business operations, and damage our reputation, which might further cause the common stock to significantly decline in value or become worthless. See “Risk Factors — Risks Related to Doing Business in Hong Kong,” the section “Our Company” in the Prospectus Summary and “Permission Required from the PRC Authorities” in the Regulation section.

The securities offered by this prospectus involve a high degree of risk. See “Risk Factors” beginning on page 2, in addition to Risk Factors contained in the applicable prospectus supplement.

We may offer the securities directly or through agents or to or through underwriters or dealers. If any agents or underwriters are involved in the sale of the securities their names, and any applicable purchase price, fee, commission, or discount arrangement between or among them, will be set forth, or will be calculable from the information set forth, in an accompanying prospectus supplement. We can sell the securities through agents, underwriters, or dealers only with delivery of a prospectus supplement describing the method and terms of the offering of such securities. See “Plan of Distribution.”

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

This prospectus is dated September 18, 2026

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You should rely only on the information contained or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference into this prospectus. If any person does provide you with information that differs from what is contained or incorporated by reference in this prospectus, you should not rely on it. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You should assume that the information contained in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information contained in any document we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or any sale of a security. These documents are not an offer to sell or a solicitation of an offer to buy these securities by anyone in any jurisdiction in which such offer or solicitation is not authorized, or in which the person is not qualified to do so or to any person to whom it is unlawful to make such offer or solicitation.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of proceeds of \$75,000,000. This prospectus describes the general manner in which our securities may be offered by this prospectus. We may sell our securities through underwriters or dealers, “at-the-market” to or through a market maker, into an existing trading market or otherwise directly to one or more purchasers or through agents or through a combination of methods of sale. The identities of such underwriters, dealers, market makers or agents, as the case may be, will be described in one or more supplements to this prospectus. The securities may be offered at prices and on terms described in one or more supplements to this prospectus. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus or in documents incorporated by reference in this prospectus. The prospectus supplement that contains specific information about the terms of the securities being offered may also include a discussion of certain U.S. Federal income tax consequences and any risk factors or other special considerations applicable to those securities. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus or in documents incorporated by reference in this prospectus, you should rely on the information in the prospectus supplement. You should carefully read both this prospectus and any prospectus supplement together with the additional information described under “Where You Can Find More Information” before buying any securities in this offering.

Unless the context otherwise requires, references to “we,” “our,” “us,” “NIKI” or the “Company” in this prospectus mean NIKI BIOSOLUTIONS, INC., a Delaware corporation, on a consolidated basis with its wholly owned subsidiaries, including DiamiR, as applicable.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents and information incorporated by reference in this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are based on our management's beliefs and assumptions and on information currently available to our management. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact.

All statements in this prospectus and the documents and information incorporated by reference in this prospectus that are not historical facts are forward-looking statements. We may, in some cases, use terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions or the negative of such items that convey uncertainty of future events or outcomes to identify forward-looking statements.

Forward-looking statements are made based on management's beliefs, estimates and opinions on the date the statements are made, and we undertake no obligation to update forward-looking statements if these beliefs, estimates and opinions or other circumstances should change, except as may be required by applicable law. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Forward-looking statements are those that do not relate strictly to historical or current facts. Examples of forward-looking statements may include, among others, statements regarding the Company's:

- the initiation, timing, progress and results of our preclinical and clinical trials, and our research and development programs;
- our ability to advance our drug candidates into, and successfully complete, clinical trials;
- our ability to identify and develop new drug and device candidates;
- our reliance on the success of our drug candidates currently undergoing preclinical development; in particular, our Lead Project candidates;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our drug and device candidates, if approved;
- our ability to develop sales and marketing capabilities;
- the pricing and reimbursement of our drug candidates, if approved;
- the implementation of our business model, strategic plans for our business and technology;

- the scope of protection we are able to establish and maintain for IP rights covering our drug and device candidates and technology;
- our ability to operate our business without infringing the IP rights and proprietary technology of other parties;
- costs associated with defending IP infringement, product liability and other claims;
- regulatory development in the U.S., Europe and PRC and other jurisdictions;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional grant funding; the rate and degree of market acceptance of our drug and device candidates;
- developments relating to our competitors and industry, including competing therapies;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance;
- the future trading price of our Common Stock and impact of securities analysts' reports on these prices; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity and development of the industry in which the Company operates may differ materially from those made in or suggested by the forward-looking statements. Therefore, investors should not rely on any of these forward-looking statements. Factors that may cause actual results to differ materially include changes in the markets in which the Company operates, customer demand, the financial markets, economic, business and regulatory and other factors, such as the Company's ability to execute on its strategy. More detailed information about risk factors can be found under the section "Risk Factors" included herein and in other reports filed by the Company, including reports on Form 8-K. The Company does not undertake any duty to update forward-looking statements after the date they are made, except as required by law.

ABOUT NIKI

Overview

On July 20, 2026 (the “Closing Date”), after obtaining the requisite shareholder approval and satisfying the closing conditions, Niki BioSolutions, Inc. (formerly known as Aptorum Group Limited, a Cayman Islands exempted company with limited liability (“Aptorum”)) consummated its previously announced merger (the “Closing”) pursuant to that certain Agreement and Plan of Merger on July 14, 2025, (the “Merger Agreement”), between Aptorum and Diamir Biosciences Corp., a Delaware corporation (“Diamir”), pursuant to which, among other matters, Aptorum was to form a direct, wholly owned subsidiary in the state of Delaware (“Merger Sub”).

Pursuant to the terms of the Merger Agreement, immediately prior to the Closing on July 20, 2026, Aptorum affected a domestication under Section 388 of the General Corporation Law of the State of Delaware (the “DGCL”) and Section 206 of the Companies Act (as revised) of the Cayman Islands (the “Domestication”), pursuant to which Aptorum transferred by way of continuation to and became a Delaware corporation. On July 20, 2026, immediately following the Domestication, Merger Sub merged with and into Diamir in accordance with the applicable provisions of the DGCL, with Diamir continuing as the surviving company and a wholly-owned subsidiary of Aptorum (the “Merger”). As part of the Domestication, Aptorum changed its name to Niki BioSolutions, Inc. (the “Company” or “Niki”) and filed Niki’s Certificate of Incorporation with the Delaware Secretary of State, which replaced Aptorum’s memorandum and articles in effect as of such time. In connection with the Merger, the Common Stock, trades on Nasdaq under the symbol “NIKI”. In connection with the name change, the CUSIP number for the Common Stock is 653942 102.

Following the Domestication, each of Aptorum’s then issued and outstanding Class A ordinary share, par value \$0.00001 per share (the “Aptorum Class A ordinary shares”) converted automatically, on a one-for-one basis, into a share of our Common Stock, and each then issued and outstanding Class B ordinary share of Aptorum converted automatically into a share of our Common Stock and a share of Niki’s non-voting and non-convertible Series A preferred stock (the “Series A Preferred Stock”).

Pursuant to the Merger, each then-outstanding share of Diamir’s common stock was converted into a number of shares of our Common Stock equal to the Conversion Ratio, which was the number resulting from dividing (i) 0.4102, which is the quotient of dividing the total number of Aptorum’s Class A ordinary shares on a fully diluted basis by the total number of shares of Diamir common stock on a fully diluted basis, by (ii) three-sevenths (3/7). Following the Merger, Diamir became a wholly owned subsidiary of Niki.

Niki BioSolutions is a clinical-stage life sciences company focused on unmet medical needs and high-quality genomic and biomarker testing solutions to healthcare providers, research institutions, and life sciences organizations through its CLIA-certified, CAP-accredited laboratory. The company combines proprietary technologies with a commitment to scientific rigor to support precision medicine across a range of therapeutic areas, including brain health and oncology. Niki BioSolutions collaborates with leading academic centers, disease foundations, and biopharma companies.

Our Common Stock is currently listed on The Nasdaq Capital Market under the symbol “NIKI.”

The rights of holders of our Common Stock are governed by our certificate of incorporation (the “Charter”), our bylaws (the “Bylaws”) and the Delaware General Corporation Law (the “DGCL”).

Our principal executive offices are located at 116 Village Boulevard, Suite 200, Princeton, NJ 08540. Our telephone number is (609)-951-2222.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting Common Stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting Common Stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the risks, uncertainties and other factors described below. In the following paragraphs, the Company describes some of the principal risks and uncertainties that could adversely affect its business, results of operations, financial condition (including capital and liquidity), or prospects or the value of or return on an investment in the Company. These risks and uncertainties, however, are not the only ones faced by the Company. Other risks and uncertainties that are not presently known to the Company that it has failed to identify, or that it currently considers immaterial may adversely affect the Company as well. Except where otherwise noted, the risk factors address risks and uncertainties that may affect the Company as well as its subsidiaries, including DiamiR.

DiamiR has never generated revenue from product sales and all of DiamiR's product candidates are currently in the pre-commercial stage, and DiamiR may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.

DiamiR is a molecular diagnostic company focused on developing minimally invasive tests for early detection and monitoring of Mild Cognitive Impairment, Alzheimer's, Parkinson's, other neurodegenerative diseases, and cancer. The proprietary technology they developed is based on quantitative analysis of circulating organ-enriched microRNAs in plasma. Short-term objectives of the Company include the development of Lab-Developed tests (LDTs) in its CLIA licensed lab based on the identified miRNA expression signatures. The tests could also be used for patient screening and stratification, as well as disease and treatment monitoring. DiamiR has devoted most of its financial resources to conducting studies on analysis of circulating organ-enriched miRNA biomarkers and building its patent portfolio. DiamiR has not generated any revenues from product sales. DiamiR's ability to fully develop its products and market them successfully is depending on many factors, some of which are out of their control and many of which are described elsewhere in this prospectus. Although DiamiR has received revenue in the past from providing testing services to life sciences companies, and may again in the future, they cannot be certain that such services will bring sufficient revenue to support its operation and R&D. Thus, DiamiR may not be able to generate a profit until its product candidates become profitable, which may never occur.

There is substantial doubt about DiamiR's ability to continue as a going concern.

DiamiR's auditor have indicated in their audit opinion there is substantial doubt as to DiamiR's ability to continue as a going concern in their audit report on its audited financial statements for the year ended May 31, 2026. Since its inception in December 2009, DiamiR's operations have been funded through capital contributions of its founders as well as grant funding received through the government agencies and a private foundation. DiamiR's management believes this capital is insufficient to fund its operations for the next twelve months and does not anticipate that DiamiR's existing working capital alone will be sufficient to fund its operations through the successful development and commercialization of products. As a result, DiamiR will need additional capital to fund its operations and continue to conduct activities to support its product development and commercialization activities. DiamiR's failure to raise additional funds may require DiamiR to suspend or cease its activities altogether which could result in the loss of your investment.

If we fail to raise additional capital, our ability to implement our business model and strategy could be compromised.

We have limited capital resources and operations. To date, DiamiR's operations have been funded entirely from the proceeds from equity financings, loans from shareholders or grants and we expect to require substantial additional capital in the near future to develop and market new products, services and technologies for the Company and our subsidiaries, as well as for funding expenses for research and development ("R&D"), and compensation of our executive management and employees. These projected operating expenses are based solely on our rough estimates and do not include any extraordinary items or expenditures, which may be incurred from time to time during the course of its business.

Accordingly, if we do not receive additional financing in the future, we may be unable to carry out our full business plan. We do not currently have any commitments for financing to meet our expected needs and we may not be able to obtain additional financing on terms acceptable to it, or at all. Even if we obtain financing for our near-term operations and product development, we expect that we will require additional capital beyond the near term. If we are unable to raise capital when needed, our business, financial condition and results of operations would be materially adversely affected, and we could be forced to reduce or discontinue our operations.

If we borrow money to expand our business, the likelihood that investors may lose some or all of their investment may increase.

We anticipate that we may incur debt for financing our growth. Our ability to borrow funds will depend upon a number of factors, including the condition of the financial markets. If we receive debt financing, we will have priority in any liquidation over the claims of holders of our stockholders, which could increase the risk of loss of your investment. In addition, our payment obligations with respect to any indebtedness could divert funds away from our operations, marketing and product development efforts.

Anti-takeover provisions in the Company's Charter and Bylaws and under Delaware law could make an acquisition of the Company, which may be beneficial to its stockholders, more difficult and may prevent attempts by its stockholders to replace or remove the Company's management.

The Company's Charter and Bylaws, as well as the DGCL contains provisions that could make it more difficult for a third party to acquire the Company, even if doing so might be beneficial to the Company's stockholders. Among other things, these provisions include:

- allow the Board to authorize the issuance of undesignated preferred stock, the terms of which may be established and the shares of which may be issued without stockholder approval, and which may include supermajority voting, special approval, dividend, or other rights or preferences superior to the rights of other stockholders;
- provide that, at any time, directors may only be removed with or without cause, and only by the affirmative vote of holders of a majority in voting power of all the then-outstanding shares of Company Common Stock entitled to vote thereon, voting together as a single class;
- provide that special meetings may only be called by or at the direction of the Chairman of the Company Board, the Company Board or the Chief Executive Officer or president or upon the written request by a majority of the shareholders entitled to vote;
- provide that any alteration, amendment or repeal, in whole or in part, of any provision of the Proposed Bylaws by Company's stockholders will require the affirmative vote of the holders of at least 66⅔% in voting power of all the then-outstanding shares of the Company Common Stock entitled to vote thereon, voting together as a single class; and
- establish advance notice requirements for nominations for elections to the Company Board and for proposing matters that can be acted upon by stockholders at stockholder meetings.

Section 203 of the DGCL generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. The Company has expressly elected not to be governed by Section 203 of the DGCL. At that time, such election shall be automatically withdrawn and Company will thereafter be governed by Section 203 of the DGCL. These provisions could discourage, delay or prevent a transaction involving a change in control of Company. These provisions could also discourage proxy contests and make it more difficult for Company's stockholders to elect directors of their choosing and cause Company to take other corporate actions they desire, including actions that Company's stockholders may deem advantageous. In addition, because the Company Board is responsible for appointing the members of Company's management team, these provisions could in turn affect any attempt by Company's stockholders to replace current members of Company's management team.

These anti-takeover provisions and other provisions in the Charter, Bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of the Company Board or initiate actions that are opposed by Company's then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving Company. The existence of these provisions could negatively affect the price of Company Common Stock and limit opportunities for a stockholder to realize value in a corporate transaction. In addition, if prospective takeovers are not consummated for any reason, Company may experience negative reactions from the financial markets, including negative impacts on the price of Company Common Stock.

Our Charter designates the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by Company's stockholders and the federal district courts of the United States as the exclusive forum for litigation arising under the Securities Act, which could limit Company's stockholders' ability to obtain a favorable judicial forum for disputes with Company.

Pursuant to our current Charter, unless it consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom, will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on Company's behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of Company's current or former directors, officers, employees or stockholders to Company or its stockholders; (iii) any action asserting a claim against Company or any of its current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, the Proposed Charter or the Proposed Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the Proposed Charter or the Proposed Bylaws; (v) any action or proceeding asserting a claim against Company or any of its current or former directors, officers, employees or stockholders as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware and (vi) any action asserting an "internal corporate claim," as that term is defined in Section 115 of the DGCL; provided that, for the avoidance of doubt, the foregoing forum selection provision will not apply to claims arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

The Proposed Charter will also provide that, unless Company consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The Proposed Charter will further provide that any person or entity purchasing or otherwise acquiring any interest in shares of Company Common Stock is deemed to have notice of and consented to the provisions of the Proposed Charter described above.

The forum selection provisions in the Proposed Charter may have the effect of discouraging lawsuits against the Company's directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings and there is uncertainty as to whether a court would enforce such provisions. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If the enforceability of the Company's forum selection provisions were to be challenged, it may incur additional costs associated with resolving such challenge. While the Company currently has no basis to expect any such challenge would be successful, if a court were to find its forum selection provisions to be inapplicable or unenforceable with respect to one or more of these specified types of actions or proceedings, the Company may incur additional costs associated with having to litigate in other jurisdictions, which could result in a diversion of the time and resources of the Company's employees, management and board of directors, and could have an adverse effect on its business, financial condition and results of operations.

Risks related to our 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 common stock, 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%), 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, CMPR 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, CMPR 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, CMPR 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 operation

Risks Related to Our 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. The timing and scope of advancing both ALS-4 Phase 2 clinical trials and SACT-1 Phase 1/2 trials are contingent upon securing appropriate collaborative partnerships and adequate funding resources. The Company is actively seeking strategic collaborators who can provide both financial support and clinical expertise to advance these therapeutic programs. 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 Intellectual Properties

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 prospectus, 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 research, 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 common stock. 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 prospectus. 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 “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 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 common stock 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 hereof, we have 2 full-time employees, one of whom is the Chief Executive Officer and the other who is engaged in general and administrative functions and who is located in Asia. In addition, we have engaged and may continue to engage independent contracted consultants and advisors to assist us with our operations. As our development and commercialization plans and strategies develop, 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 common stock. 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, 2025, 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 taken 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, 2025. 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, 2025. Investors may lose confidence in our operating results, the price of the Our common stock 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, Our common stock 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.

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 common stock.

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 common stock.

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 employees. 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 \$3.5 million and 0.9 million as of December 31, 2025 and 2024, 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 "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 common stock. A trading prohibition for our common stock, 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 herein, is headquartered in Manhattan, New York, with an address of 7 Penn Plaza, Suite 830, New York, New York 10001, 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. 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. Our auditor’s audit working papers are not located in China. 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 common stock could be issued shortly after our filing of the second consecutive annual report on Form 10-K for which we have retained a PCAOB Identified Firm.

If our common stock are subject to a trading prohibition under the HFCA Act, the price of our common stock 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 common stock when you wish to do so. Furthermore, if we are able to maintain a listing of our common stock on a non-U.S. exchange, investors owning our common stock 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.

Risks Related to Our Corporate Structure

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

One of our directors, Dr. Sheinerman, has voting rights with respect to an aggregate of 1,515,293 shares of Common Stock, representing approximately 51.6% of the voting power of our outstanding common stock as of the date hereof. As a result, Dr. Sheinerman 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. As a board member, Dr. Sheinerman owes a fiduciary duty to our shareholders and must act in good faith in a manner she reasonably believes to be in the best interests of our shareholders. As a shareholder, even a controlling shareholder, Dr. Sheinerman is entitled to vote her shares, and shares over which she has voting control as a result of voting agreements, in her own interests, which may not always be in the interests of our shareholders generally. However, Dr. Sheinerman is a party to that certain Stockholders Agreement dated as of July 20, 2026, pursuant to which she has agreed to vote in favor of certain corporate actions for a certain period of time, all as detailed in the Stockholders Agreement, a copy of which is attached as an exhibit to the Current Report on Form 8-K filed on July 20, 2026, which is incorporated herein by reference.

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 common stock 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.

We hold a 97.27% economic interest and 31.51% voting power in Libra, while Nautilus International Group Limited (an independent third party) (“Nautilus”) holds 68.26% of Libra’s voting power. Our economic interest is based on owning 7,700,000 shares of Libra’s Class A Common Stock and our voting power is based on the combination of those shares and 2,000,000 shares of Libra’s Class B Common Stock that we own. Each share of Libra’s Class A Common Stock is entitled to one vote and each share of Libra’s Class B Common Stock is entitled to ten votes. We do not consider ourselves to be the primary beneficiary over Libra and therefore do not currently consolidate Libra into our financial statements. This determination is based on U.S. GAAP requirements, which state that the Group has a variable interest (or combination of variable interests) if the interest provides the Company with (a) the power to direct the activities that most significantly impact Libra’s economic performance and (b) the obligation to absorb losses or right to receive benefits that could be potentially significant to Libra. The Group continually reassesses whether it is the primary beneficiary of a VIE throughout the entire period the Group is involved with the VIE. Under Libra’s second amended and restated articles of association (“Libra’s A&A”), we, as a holder hold approximately 97.27% of Libra’s paid-up share capital (as to Issue Price) of shares, have the ability to appoint and remove directors. Subject to and insofar as permitted by provisions of the Law, Nautilus, as a holder hold 68.26% of Libra’s voting power giving the right to attend and vote at general meetings, may from time to time by Ordinary Resolution alter or amend Libra’s A&A or alter the size of Libra’s board of directors. Mr. Chan Kin Wai is the sole shareholder and director of Nautilus, and he has never been affiliated with our Company. As a result, through the Board of Directors, in accordance with ASC 810-10-25-38A(a), Nautilus has the power to direct those activities that most significantly impact Libra’s economic performance. (See, “*History and Development of the Company*” on page 117 for further details about our relationship with Libra.) Additionally, although we hold a 97.27% economic interest in Libra that creates an obligation to absorb Libra’s losses and rights to receive benefits, Libra ceased operations in 2023. Therefore no such losses or benefits are significant to Libra. Accordingly, we determined that at least currently, we are not the primary beneficiary of Libra. As a result, Libra’s financial results are not consolidated into 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. This could be because Libra is indebted to us and its operational performance or inability to generate sufficient cash flows. The Company’s maximum exposure to loss resulting from its involvement with Libra is nil for the year ended December 31, 2025 and the year ended December 31, 2024.

Risks Related to Our Securities

If we fail to comply with the continued listing requirements of Nasdaq Capital Market, 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 July 31, 2023, the Company requested to transfer its Aptorum 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 Aptorum Class A ordinary shares to the Nasdaq Capital Market. The Company’s securities were transferred to the Nasdaq Capital Market at the opening of business on August 10, 2023, and the trading activities of Aptorum Class A ordinary shares was not 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 October 14, 2025, to regain compliance with the continued listing requirements. The Company was notified that it regained compliance on August 4, 2025.

If the Company fails to comply with any 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.

Our common stock eligible for future sale may adversely affect the market price of our common stock if the shares are successfully listed on the Nasdaq Capital Market or other stock markets, as the future sale of a substantial amount of outstanding common stock in the public marketplace could reduce the price of our common stock.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock 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 common stock. An aggregate of 2,938,625 shares of common stock are outstanding as of the date hereof and all of them are freely transferable without restriction or further registration under the Securities Act.

A sale or perceived sale of a substantial number of our common stock may cause the price of our common stock to decline.

If our shareholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. Moreover, the perceived risk of this potential dilution could cause shareholders to attempt to sell their shares and investors to short our common stock. 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 such preferred shares, could negatively impact the value of our common stock 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 shares of common stock.

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 common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future, and any return on investment may be limited to the value of our common stock. 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 the General Corporation Law of the State of Delaware, dividends may be declared and paid only out of surplus (the excess of net assets over capital) or, in the absence of surplus, out of net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. A dividend may not be paid if, after giving it effect, the Company would be unable to pay its debts as they fall due in the ordinary course of business.

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 common stock. 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 common stock 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.

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, 2025, 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.

We may not be able to maintain an active, liquid and orderly trading market for our common stock and our stock price may be volatile.

Active, liquid and orderly trading markets usually result in less price volatility and more efficiency in carrying out investors' purchase and sale orders. The market price of our common stock could vary significantly as a result of a number of factors, some of which are beyond our control. In the event of a drop in the market price of our common stock, you could lose a substantial part or all of your investment in our shares.

The following factors could affect our share price:

- our operating and financial performance;
- quarterly variations in the rate of growth of our financial indicators, such as net income per share, net income and revenues;
- the public reaction to our press releases, our other public announcements and our filings with the SEC;
- strategic actions by our competitors;
- changes in revenue or earnings estimates, or changes in recommendations or withdrawal of research coverage, by equity research analysts;
- speculation in the press or investment community;
- the failure of research analysts to cover our securities;
- sales of our common stock by us or other shareholders, or the perception that such sales may occur;
- changes in accounting principles, policies, guidance, interpretations or standards;
- additions or departures of key management personnel;
- actions by our shareholders;
- domestic and international economic, legal and regulatory factors unrelated to our performance; and
- the realization of any risks describes under this "Risk Factors" section.

The stock markets in general have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. Such litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources and harm our business, operating results and financial condition.

Risks Related to Our Doing Business in Hong Kong

Our company currently does not have operations in mainland China. PRC laws and regulations are applicable to a company such as us and 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 common stock, to significantly decline or become worthless.

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 prospectus, we maintain a significant portion 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 principal business operations are 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 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 common stock 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 PCAOB continues to demand complete access in mainland China and Hong Kong moving forward and has resumed regular inspections since March 2023. The PCAOB is continuing pursuing ongoing investigations and may 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. 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.

If the PCAOB is unable to inspect and investigate completely registered public accounting firms located in China in 2023 and beyond, or if we fail to, among others, meet the PCAOB's requirements, including retaining a registered public accounting firm that the PCAOB determines it is able to inspect and investigate completely, we will be identified as a "Commission-identified Issuer," and upon the expiration of the applicable years of non-inspection under the HFCAA and relevant regulations, our shares will be delisted and will not be permitted for trading over the counter. Such a delisting or prohibition would substantially impair your ability to sell or purchase our shares, and the risk and uncertainty associated with delisting would have a negative impact on the price of our share. Moreover, the HFCAA or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of our shares could be adversely affected. Such a prohibition would significantly affect our ability to raise capital on terms acceptable to us, or at all, which would have a material adverse impact on our business, financial condition, and prospects.

The SEC is assessing how to implement other requirements of the HFCAA, including the listing and trading prohibition requirements described above. Future developments in respect of increasing U.S. regulatory access to audit information are uncertain, as the legislative developments are subject to the legislative process and the regulatory developments are subject to the rule-making process and other administrative procedures.

While the CSRC, the SEC and the PCAOB have entered into the SOP Agreements regarding the inspection of PCAOB-registered accounting firms in Mainland China, there can be no assurance that we will be able to comply with requirements imposed by U.S. regulators if there is significant change to current political arrangements between Mainland China and Hong Kong, or if any component of our auditor's work papers become located in Mainland China in the future. Delisting of our shares would force holders of our shares to sell their shares. The market price of our shares could be adversely affected as a result of anticipated negative impacts of these executive or legislative actions upon, regardless of whether these executive or legislative actions are implemented and regardless of our actual operating performance.

If or our subsidiaries were to be required to obtain any permission or approval from or complete any filing procedure with the China Securities Regulatory Commission (the "CSRC"), the CAC, or other PRC governmental authorities in connection with the business combination or future offerings under PRC laws, we and/or our subsidiaries may be fined or subject to other sanctions, and our subsidiaries' business and our reputation, financial condition, and results of operations may be materially and adversely affected.

The Cybersecurity Review Measures jointly promulgated by the CAC and other relevant PRC governmental authorities on December 28, 2021 required that, among others, "critical information infrastructure" or network platform operators holding over one million users' personal information to apply for a cybersecurity review before any public offering on a foreign stock exchange. However, this regulation is recently issued and there remain substantial uncertainties about its interpretation and implementation.

As of the date of this prospectus, we and our subsidiaries do not have any business operation or maintain any office or personnel in mainland China. We and our subsidiaries have not collected, stored, or managed any personal information in mainland China. Based on the assessment conducted by the management, we believe that we and our subsidiaries are not currently required to proactively apply to a cybersecurity review for the business combination or future offerings overseas, on the basis that (i) our subsidiaries are incorporated in the State of Delaware, Hong Kong, the Cayman Islands, and other jurisdictions outside of mainland China and operate in Hong Kong without any subsidiary or variable interest entities (“VIE”) structure in mainland China, and we do not maintain any office or personnel in mainland China; (ii) except for the Basic Law, the National Laws 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, and 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, and PRC laws and regulations relating to data protection and cyber security have not been listed in Annex III as the date of this proxy are solely carried out by our overseas entities outside of mainland China for the purpose of offering services in Hong Kong and other jurisdictions outside of mainland China; (iv) we and our subsidiaries do not control more than one millions users’ personal information as of the date of this prospectus; (v) as of the date of this prospectus, we and our subsidiaries have not received any notice of identifying us as critical information infrastructure from any relevant PRC governmental authorities; and (vi) as of the date of this prospectus, none of us or our subsidiaries have been informed by any PRC governmental authority of any requirement for a cybersecurity review.

Additionally, we believe that we and our subsidiaries are compliant with the regulations and policies that have been issued by the CAC to date and there was no material change to these regulations and policies since the business combination. Based on the above thorough review of applicable laws and regulations, we have concluded that neither we nor our subsidiaries are required to obtain permissions or approvals from the China Securities Regulatory Commission (CSRC), the Cyberspace Administration of China (CAC), or any other PRC governmental authority to operate our business or offer securities to foreign investors. The Company only conducts very basic business — administrative, corporate governance — in Hong Kong and therefore, other than our business registration from Inland Revenue Department for tax registration, we do not need any permissions or approvals to operate our business and we affirmatively state that we have received all requisite permissions or approvals necessary to operate our business, and can affirmatively state that no related permissions or approvals have been denied. However, regulatory requirements on cybersecurity and data security in the mainland China are constantly evolving and can be subject to varying interpretations or significant changes, which may result in uncertainties about the scope of our responsibilities in that regard, and there can be no assurance that the relevant PRC governmental authorities, including the CAC, would reach the same conclusion as us. We will closely monitor and assess the implementation and enforcement of the Cybersecurity Review Measures. If the Cybersecurity Review Measures mandates clearance of cybersecurity and/or data security regulators and other specific actions to be completed by companies like us, we may face uncertainties as to whether we can meet such requirements timely, or at all.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the “Trial Measures”) and five supporting guidelines, which took effect on March 31, 2023. The Trial Measures requires companies in mainland China that seek to offer and list securities overseas, both directly and indirectly, to fulfill the filing procedures with the CSRC. According to the Trial Measures, the determination of the “indirect overseas offering and listing by companies in mainland China” shall comply with the principle of “substance over form” and particularly, an issuer will be required to go through the filing procedures under the Trial Measures if the following criteria are met at the same time: (i) 50% or more of the issuer’s operating revenue, total profits, total assets or net assets as documented in its audited consolidated financial statements for the most recent accounting year are accounted for by companies in mainland China; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main places of business are located in mainland China, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in mainland China. On the same day, the CSRC held a press conference for the release of the Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies, which clarifies that (i) on or prior to the effective date of the Trial Measures, companies in mainland China that have already submitted valid applications for overseas offering and listing but have not obtained approval from overseas regulatory authorities or stock exchanges shall complete the filing before the completion of their overseas offering and listing; and (ii) companies in mainland China which, prior to the effective date of the Trial Measures, have already obtained the approval from overseas regulatory authorities or stock exchanges and are not required to re-perform the regulatory procedures with the relevant overseas regulatory authority or stock exchange, but have not completed the indirect overseas listing, shall complete the overseas offering and listing before September 30, 2023, and failure to complete the overseas listing within such six-month period will subject such companies to the filing requirements with the CSRC.

Based on the assessment conducted by the management, we are not subject to the Trial Measures, because we are incorporated in the State of Delaware and our subsidiaries are incorporated in the State of Delaware, Hong Kong, the Cayman Islands and other regions outside of mainland China and operate in Hong Kong without any subsidiary or VIE structure in mainland China, and we do not have any business operations or maintain any office or personnel in mainland China. However, as the Trial Measures and the supporting guidelines are newly published, there exists uncertainty with respect to the implementation and interpretation of the principle of “substance over form”. As of the date of this prospectus, there was no material change to these regulations and policies since the business combination. If our future securities offerings, and our listing on Nasdaq were later deemed as “indirect overseas offering and listing by companies in mainland China” under the Trial Measures, we may need to complete the filing procedures for our business combination and future secondary offerings, and listing. If we are subject to the filing requirements, we cannot assure you that we will be able to complete such filings in a timely manner or even at all.

Since these statements and regulatory actions are new, it is also highly uncertain in the interpretation and the enforcement of the above cybersecurity and overseas listing laws and regulation. There is no assurance that the relevant PRC governmental authorities would reach the same conclusion as us. If we and/or our subsidiaries are required to obtain approval or filings from any governmental authorities, including the CAC and/or the CSRC, in connection with the listing or continued listing of our securities on a stock exchange outside of Hong Kong or mainland China, it is uncertain how long it will take for us and/or our subsidiaries to obtain such approval or complete such filing, and, even if we and our subsidiaries obtain such approval or complete such filing, the approval or filing could be rescinded. Any failure to obtain or a delay in obtaining the necessary permissions from or complete the necessary filing procedure with the PRC governmental authorities to conduct offerings or list outside of Hong Kong or mainland China may subject us and/or our subsidiaries to sanctions imposed by the PRC governmental authorities, which could include fines and penalties, suspension of business, proceedings against us and/or our subsidiaries, and even fines on the controlling shareholder and other responsible persons, and our subsidiaries’ ability to conduct our business, our ability to invest into mainland China as foreign investments or accept foreign investments, or our ability to list on a U.S. or other overseas exchange may be restricted, and our subsidiaries’ business, and our reputation, financial condition, and results of operations may be materially and adversely affected.

If we and/or our subsidiaries were to be required to comply with cybersecurity, data privacy, data protection, or any other PRC laws and regulations related to data and we and/or our subsidiaries cannot comply with such PRC laws and regulations, our subsidiaries’ business, financial condition, and results of operations may be materially and adversely affected.

We may be subject to a variety of cybersecurity, data privacy, data protection, and other PRC laws and regulations related to data, including those relating to the collection, use, sharing, retention, security, disclosure, and transfer of confidential and private information, such as personal information and other data. These laws and regulations apply not only to third-party transactions, but also to transfers of information within our organization. These laws and regulations may restrict our subsidiaries’ business activities and require us and/or our subsidiaries to incur increased costs and efforts to comply, and any breach or noncompliance may subject us and/or our subsidiaries to proceedings against such entity(ies), damage our reputation, or result in penalties and other significant legal liabilities, and thus may materially and adversely affect our subsidiaries’ business and our financial condition and results of operations.

As the laws and regulations related to cybersecurity, data privacy, and data protection in mainland China where our subsidiaries do not have operations are relatively new and evolving, and their interpretation and application may be uncertain, it is still unclear if we and/or our subsidiaries may become subject to such new laws and regulations.

The PRC Data Security Law, or the Data Security Law, which was promulgated by the Standing Committee of the National People’s Congress on June 10, 2021 and took effect on September 1, 2021, requires data collection to be conducted in a legitimate and proper manner, and stipulates that, for the purpose of data protection, data processing activities must be conducted based on data classification and hierarchical protection system for data security. According to Article 2 of the Data Security Law, it applies to data processing activities within the territory of mainland China as well as data processing activities conducted outside the territory of mainland China which jeopardize the national interest or the public interest of China or the rights and interest of any PRC organization and citizens. Any entity failing to perform the obligations provided in the Data Security Law may be subject to orders to correct, warnings and penalties including ban or suspension of business, revocation of business licenses or other penalties. As of the date of this prospectus, we do not have any operation or maintain any office or personnel in mainland China, and we have not conducted any data processing activities which may endanger the national interest or the public interest of China or the rights and interest of any Chinese organization and citizens. Therefore, we do not believe that the Data Security Law is applicable to us.

On August 20, 2021, the Standing Committee of the National People's Congress of China promulgated the Personal Information Protection Law, which integrates the scattered rules with respect to personal information rights and privacy protection and took effect on November 1, 2021. According to Article 3 of the Personal Information Protection Law, it is applied not only to personal information processing activities carried out in the territory of mainland China but also to personal information processing activities outside the mainland China for the purpose of offering products or services to domestic natural persons in the territory of mainland China. The offending entities could be ordered to correct, or to suspend or terminate the provision of services, and face confiscation of illegal income, fines or other penalties. As our subsidiaries' services are provided in Hong Kong rather than in the mainland China to clients worldwide, including but not limited to clients of mainland China who visit our offices in these locations, we take the view that we and our subsidiaries are not subject to the Personal Information Protection Law.

On July 7, 2022, the Cyberspace Administration of China (the "CAC") issued the Measures for Security Assessment of Outbound Data Transfer, or the Measures, which took effect on September 1, 2022. According to the Measures, in addition to the self-risk assessment requirement for provision of any data outside mainland China, a data processor shall apply to the competent cyberspace department for data security assessment and clearance of outbound data transfer in any of the following events: (i) outbound transfer of important data by a data processor; (ii) outbound transfer of personal information by an operator of critical information infrastructure or a data processor which has processed more than one million users' personal data; (iii) outbound transfer of personal information by a data processor which has made outbound transfers of more than one hundred thousand users' personal information or more than ten thousand users' sensitive personal information cumulatively since January 1 of the previous year; (iv) such other circumstances where ex-ante security assessment and evaluation of cross-border data transfer is required by the CAC. As of the date of this prospectus, we and our subsidiaries have not collected, stored, or managed any personal information in mainland China. Therefore, we believe that the Measures is not applicable to us.

However, given the recency of the issuance of the above PRC laws and regulations related to cybersecurity and data privacy, we and our subsidiaries still face uncertainties regarding the interpretation and implementation of these laws and regulations and we could not rule out the possibility that any PRC governmental authorities may subject us and/or our subsidiaries to such laws and regulations in the future. If they are deemed to be applicable to us and/or our subsidiaries, we cannot assure you that we and our subsidiaries will be compliant with such new regulations in all respects, and we and/or our subsidiaries may be ordered to rectify and terminate any actions that are deemed illegal by the PRC governmental authorities and become subject to fines and other government sanctions, which may materially and adversely affect our subsidiaries' business and our financial condition and results of operations.

The Chinese government maintains oversight and control over offerings that are conducted overseas and/or foreign investment in mainland China-based issuers to Hong Kong-based issuers, such action may significantly limit or completely hinder our ability to offer or continue to offer Common Stock to investors and cause the value of our Common Stock to significantly decline or be worthless, it could also result in a material change to our operations.

Recent statements, laws and regulations by the Chinese government, including the Measures for Cybersecurity Review (2021), the PRC Personal Information Protection Law and the Trial Measures, have indicated an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investments in China-based issuers. It is uncertain whether the Chinese government will adopt additional requirements. We could be subject to approval or review of Chinese regulatory authorities to pursue future offerings. Any future action by the PRC government expanding the categories of industries and companies whose foreign securities offerings are subject to review by the CSRC or CAC or filing with the CSRC could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and could cause the value of such securities to significantly decline or be worthless, it could also result in a material change to our operations.

The enforcement of laws and rules and regulations in the PRC can change quickly with little advance notice. Additionally, the PRC laws and regulations and the enforcement of such that apply or are to be applied to Hong Kong can change quickly with little or no advance notice. As a result, the Hong Kong legal system embodies uncertainties which could limit the availability of legal protections, which could result in a material change in our operating Subsidiaries' operations and/or the value of the securities we are offering.

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 currency (the 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 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 government 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 are political risks associated with conducting business in Hong Kong.

A significant portion of our operations are in Hong Kong. Accordingly, the business operations and financial conditions of our operating Subsidiaries will be affected by the political and legal developments 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 and may adversely affect our operations. 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.

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, 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 political arrangement between PRC and Hong Kong and the economic, political and legal environment in Hong Kong in the future. Since a significant portion of our operations are based in Hong Kong, any change of such political arrangements may pose an immediate threat to the stability of the economy in Hong Kong, thereby directly and adversely affecting our results of operations and financial positions.

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 the United States signed an executive order and the Hong Kong Autonomy Act and an executive order to remove the preferential trade status of Hong Kong, pursuant to § 202 of the United States-Hong Kong Policy Act of 1992. The U.S. government has determined that Hong Kong is no longer sufficiently autonomous to justify preferential treatment in relation to the PRC, especially with the issuance of the Law of the People's Republic of China on Safeguarding National Security in the Hong Kong Special Administrative Region (the "Hong Kong National Security Law") on July 1, 2020. Hong Kong will now be treated as Mainland China, in terms of visa application, academic exchange, tariffs and trading, etc. According to § 3(c) of the executive order issued on July 14, 2020, the license exception for exports and reexports to Hong Kong and transfer within the PRC is revoked, while exports of defense items are banned. On the other hand, the existing tariffs the U.S. imposed on Mainland China will also be applied to Hong Kong exports. Losing its special status, Hong Kong's competitiveness as the logistic hub may deteriorate in the future as its tax benefits as a result of preferential situation no longer exists and companies might prefer exporting through other cities. The level of activities of domestic exports and re-exports and other trading activities in Hong Kong may decline owing to the tariff being imposed on Hong Kong exports and the export restriction. 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 Common Stock could be adversely affected.

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 subsidiaries' business, our financial condition and results of operations, and/or the value of our common stock or our ability to offer or continue to offer securities to investors may be materially and adversely affected by existing or future PRC laws and regulations.

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. However, as our principal place of business was in, and members of management and our board continue to maintain an office in Hong Kong, a special administrative region of China, existing or future laws of the PRC are applicable to us, and therefore they may 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. As we are subject to PRC laws and regulations, we are 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 plans to expand our operation or acquire any operation in the mainland China. However, we are subject to the laws and regulations of the PRC. It remains uncertain as to the enactment, interpretation and implementation of regulatory requirements related to overseas securities offering and other capital markets activities and due to the possibility that laws, regulations, or policies in the PRC could change rapidly in the future, it remains uncertain whether the PRC government will adopt additional requirements that apply to our operating subsidiaries located in Hong Kong. It is also uncertain whether the Hong Kong government will be mandated by the PRC government, despite the constitutional constraints of the Basic Law, to control over offerings conducted overseas and/or foreign investment of entities in Hong Kong, including our operating subsidiaries. Any actions by the PRC government to exert more oversight and control over offerings (including 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 to significantly decline or be worthless.

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, which may result in a material change in our operations and/or the value of our common stock, 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 inconsistencies, 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; we also maintain economic interest over Libra, which is incorporated under the laws of Cayman Islands and conducted operations in Hong Kong. Since we hold a majority of Libra's outstanding Class A ordinary shares and therefore will absorb/receive portions of its expected losses or residual returns, it was determined that we maintains a variable interest in Libra; however, as stated elsewhere in this prospectus statement, we are not the primary beneficiary of Libra. Our principal executive offices are located in Princeton, New Jersey in the United States, although our Chief Executive Officer and several directors maintain an office in Hong Kong, a special administrative region of China. The PRC government influences and has discretion over the manner in which we conduct our business activities outside of mainland China.

Although we currently do not have plans to expand our operation or acquire any operation in the mainland China, we are subject to the direct intervention and influence of the PRC government, which may require a material change in our operations and/or 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 common stock 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 PRC government oversight and regulation, regardless of our actual operating performance. The Chinese government may 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 common stock, 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, 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.

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 hereof, 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 hereof, 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 hereof, 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 hereof, 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 hereof, we believe our Hong Kong subsidiaries are not required to pass the cybersecurity review of the CAC in order to list our common stock 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 hereof, we have not received any formal inquiry, notice, warning, sanction, or objection from the CSRC with respect to the listing of our common stock. 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 our Common Stock 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 hereof, we believe our Hong Kong subsidiaries are not required to obtain regulatory approval from the CSRC in order to list our common stock 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 full comply with new regulatory requirements may significantly limit or completely hinder our ability to offer or continue to offer the our common stock, 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 common stock to significantly decline in value or become worthless.

As of the date hereof, 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. We affirmatively state that to our knowledge, we have received all requisite permissions or approvals currently necessary to operate our business and no permissions or approvals have been denied. 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 our daily business operations, our ability to accept foreign investments and the listing of our common stock on a U.S. or other foreign exchanges. Since the PRC government can directly intervene or influence our operations, or exert more control through change of laws and regulations over offerings conducted overseas and/or foreign investment in issuers like us, there may be a material change in our operations and/or the value of the securities we are registering for sale and our ability to offer or continue to offer securities to investors may be significantly limited or completely hindered; the value of our common stock may also significantly decline or become worthless.

Operations in Hong Kong are subject to risks associated with the broader PRC that could adversely affect our business.

There are several risks associated with our operations in Hong Kong, including but not limited to:

- **Regulatory Changes and Governmental Control:** The PRC government has significant authority to intervene in the operations of businesses, and any changes in laws, regulations, or enforcement policies could adversely impact our operations and any future opportunities in the region.
- **Geopolitical and Economic Instability:** Ongoing tensions between the PRC and other countries, particularly the U.S., may affect trade policies, tariffs, and overall market conditions, which could disrupt our supply chain or future business in Hong Kong.
- **Currency and Capital Flow Restrictions:** We are a holding company, and as such, we conduct our operations through our subsidiaries. Cash is generally transferred through our organization as follows: the parent company may provide funding to its subsidiaries through capital contributions or intercompany loans, and subsidiaries may transfer cash to the parent company in the form of dividends or other distributions, subject to applicable laws and regulations. Currently, there are no restrictions or limitations imposed by any governmental authority in the jurisdictions where we operate, including the People's Republic of China, on the ability of our subsidiaries to transfer cash to the parent company or vice versa. We affirm that we have not experienced any difficulties or delays in transferring cash within our organization. However, if applicable laws, regulations, or interpretations change in the future, or if we inadvertently fail to comply with such requirements, we may face restrictions on transferring funds, which could adversely affect our ability to fund operations, meet financial obligations, or pay dividends to shareholders. We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future, and any return on investment may be limited to the value of our common stock. We plan to retain any future earnings to finance growth.

- Hong Kong's Evolving Legal Environment: The integration of certain aspects of Hong Kong's governance with the PRC's legal framework has created uncertainties regarding autonomy, regulatory consistency, and legal protections.

Up to December 31, 2025, we have transferred the noted amount to the referenced subsidiary:

Subsidiaries	US\$
Aptus Management Ltd	62,719,786.14
Aptorum Medical Ltd	1,624,166.03
Aptorum Therapeutics Ltd	15,369,903.99
Acticule Life Sciences Ltd	4,972,079.05
Aptorum Innovations Holding Ltd	15,087.11
Aptorum Innovations Holding Pte	442,201.61
Aptorum Group LLC	4,337.75
Claves Life Sciences Ltd	331,959.92
Scipio Life Sciences Ltd	151,710.07
Signate Life Sciences Ltd	319,385.76
Aptorum Pharmaceutical Dev. Ltd	7,300.00

Any adverse developments related to our operations in Hong Kong could have a material adverse effect on our business, financial condition, and results of operations.

Uncertainties with respect to the legal system of the People's Republic of China (the "PRC") and tax regime, including uncertainties regarding the enforcement of laws, and sudden or unexpected changes in policies, laws, and regulations in the PRC could adversely affect us.

We are subject to certain legal and operational risks associated with having operations in Hong Kong. The PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis, or at all, and may have retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. Such unpredictability towards our contractual, property and procedural rights and any failure to quickly respond to changes in the regulatory environment in the PRC could adversely affect our business, financial condition, and results of operations, and impede our ability to continue our operations in Hong Kong.

From time to time, we may have to resort to administrative and court proceedings to enforce our legal rights. Any administrative and court proceedings in mainland China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory provisions and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy, than in more developed legal systems. These uncertainties may impede our ability to enforce contracts in the PRC and could materially and adversely affect our business, financial condition, and results of operations.

The PRC government may intervene or influence our operations at any time, with little advance notice, as the PRC government deems appropriate to further regulatory, political and societal goals, which may potentially result in a material adverse effect on our operations. The enforcement of laws and rules and regulations in China can change quickly with little advance notice. Additionally, the PRC laws and regulations and the enforcement of such that apply or are to be applied to Hong Kong can change quickly with little or no advance notice. We cannot rule out the possibility that it will in the future release regulations or policies regarding our industry that could adversely affect our business, financial condition, and results of operations, as well as cause a material change in the value of our securities. Currently under the Basic Law of the Hong Kong Special Administrative Region of the PRC (the “Basic Law”), Hong Kong is self-governed by its own government under the PRC framework of “one country two systems” with a high degree of autonomy under its local constitution. We cannot assure you, however, that the PRC will maintain the “one country two systems” framework, and the PRC government may seek to further influence the business conduct of entities organized under the laws of Hong Kong, including our operations more than it currently does.

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 United 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.

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.

Risks Related to DiamiR’s Business and Operations

DiamiR is a wholly-owned subsidiary of the Company. The following risk factors relate specifically to DiamiR’s business and operations, which may materially affect the Company’s business, financial condition and results of operations

If researchers, clinicians and healthcare administrators do not adopt DiamiR's screening and diagnostic products, DiamiR will not achieve future sales growth.

DiamiR's business model is heavily reliant on the adoption of its products by researchers, clinicians, and healthcare administrators ("Industry Advocates"). These professionals play a critical role in the healthcare ecosystem, influencing both the acceptance and the utilization of new medical technologies. A failure to secure and maintain adoption among these groups poses a significant risk to DiamiR's operations. New products frequently are subject of slow adoption by healthcare specialists partly due to perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of DiamiR's future sales growth that it continues to work with key opinions leaders in the field, educate healthcare specialists about CogniMIR[®] and other assays in development, and demonstrate the clinical utility of its technology. If Industry Advocates do not believe in DiamiR's products, market acceptance of its products could fail to increase or could decrease, and its business could be harmed. Additionally, a lack of support from Industry Advocates could reduce the rate of coverage and reimbursement by both public and private third-party payors for DiamiR's products and services, which may further slow the market adoption of its product by physicians, significantly reduce its ability to achieve expected revenues and prevent DiamiR from becoming profitable. Slow adoption of DiamiR's product by Industry Advocates would significantly reduce its ability to achieve expected sales and could prevent DiamiR from achieving and maintaining profitability.

New product development and clinical validation involves a lengthy and complex process, and DiamiR may be unable to commercialize CogniMIR[®] or any other products it may develop on a timely basis, or at all.

It takes significant time to fully develop and commercialize CogniMIR[®] for risk of early neurodegeneration, and therefore its launch may be delayed or may not be successful. There can be no assurance that CogniMIR[®] will be successful in the risk assessment of Mild Cognitive Impairment and early Alzheimer's disease for a variety of technical and market reasons. DiamiR's other molecular diagnostic products, which are currently in various stages of early development, will take time to develop and commercialize, if DiamiR is able to commercialize them at all. Prior to commercializing any new products, DiamiR will need to conduct substantial research and development, including validation studies. DiamiR's product development efforts involve a high degree of risk and may fail for many reasons, including failure to demonstrate the clinical utility of the product. As DiamiR develops products, DiamiR will have to make significant investments in product development and marketing resources. In addition, competitors may develop and commercialize competing products faster than DiamiR is able to do so. If DiamiR is unable to commercialize CogniMIR[®], DiamiR may not be able to carry out its business.

DiamiR relies on a sole supplier for some of the materials used in its tests and services, and DiamiR may not be able to find replacements or transition to alternative suppliers in a timely manner.

DiamiR relies on different sole suppliers for certain materials, kits and supplies that DiamiR uses to perform its tests and services for its diagnostic tests. For example, DiamiR relies on Qiagen GmbH for its qPCR reagents and plates. DiamiR does not maintain an agreement with Qiagen GmbH; their reagents are readily available for purchase, additionally, the volume of DiamiR's business is not material to them. In addition to Qiagen, DiamiR works with other multinational stable corporations for its supplies. Although DiamiR does not currently have any agreements with other suppliers and technologies, DiamiR believes other providers, such as ThermoFisher, which offers the TaqMan qPCR kits are easily accessible and DiamiR can quickly begin working with them, if necessary. At the time of this filing all other reagents DiamiR uses are commonly available through multiple vendors on similar terms.

From time to time, DiamiR also may purchase other reagents used in its tests and services from sole-source suppliers. While DiamiR may develop alternate sourcing strategies for these materials and vendors, DiamiR cannot be certain whether these strategies will be effective, or the alternative sources will be available in a timely manner. If these suppliers can no longer provide DiamiR with the supplies DiamiR needs to perform its tests and services, if the materials do not meet DiamiR's quality specifications, or if DiamiR cannot obtain acceptable substitute materials, an interruption in test processing and services could occur. Any such interruption may directly impact DiamiR's revenue and cause DiamiR to incur higher costs.

If DiamiR cannot enter into and maintain new clinical collaborations, its efforts to commercialize CogniMIR® and its development of other products could be delayed.

DiamiR currently has several ongoing collaborations with highly regarded academic institutions in the NDs field. DiamiR's success in the future may depend in part on its ability to enter into agreements with other leading institutions in the NDs field. In the process of seeking clinical collaborations in the future DiamiR expects to engage in discussions with third parties, which may or may not lead to collaborations.

If DiamiR's clinical tests do not perform as expected in its validation studies, DiamiR may not be able to achieve widespread market adoption among physicians, which would cause its operating results, reputation, and business to suffer.

There is no guarantee that the accuracy and reproducibility DiamiR has demonstrated to date will continue in its planned clinical validation studies. As a result, the failure of DiamiR's products to perform as expected would significantly impair its operating results and its reputation. DiamiR may be subject to legal claims arising from any defects or errors in its clinical services tests.

DiamiR's ability to commercialize the diagnostic products that DiamiR develops is dependent on its relationships with laboratory services providers and support of its products.

DiamiR relies on third-party providers to draw the donor blood samples and prepare plasma in accordance with its protocol. DiamiR's business will suffer if these service providers do not support CogniMIR® or the other products that DiamiR may develop. A lack of acceptance of DiamiR's products by these service providers could result in lower test volume. DiamiR's business may suffer from the repetition of the process and increased costs.

DiamiR intends to market some of its tests as LDTs, and future changes in FDA enforcement discretion for LDTs could subject its operations to much more significant regulatory requirements.

The FDA has historically operated under a policy of enforcement discretion with respect to LDTs whereby the FDA did not actively enforce its regulatory requirements for such tests. Changes to this policy could significantly increase the costs and expenses of conducting, or otherwise harm, DiamiR's business, financial condition and results of operations. Even if such tests are authorized for marketing by the FDA, the agency could limit the test's indications for use, which may significantly limit the market for that product and may adversely affect DiamiR's business and financial condition.

DiamiR has a limited operating history, which makes it difficult to predict future prospects and financial performance.

Substantially all of DiamiR's operations are conducted through its wholly-owned subsidiary, DiamiR LLC, which started operation in September 2009. DiamiR has been operating as a consolidated company since October 1, 2014. Due to this limited operating history, it may be difficult to evaluate DiamiR's business prospects and future financial performance. As of the date of this filing, DiamiR has not yet generated revenues from its products. There is no guarantee that DiamiR will be able to generate any significant revenues. DiamiR faces numerous risks and uncertainties in the competitive markets. In particular, DiamiR has not proven that it can:

- maintain relationships with key customers and strategic partners that will be necessary to optimize the market value of its products and services;
- successfully identify and respond to emerging trends in DiamiR's market areas;
- raise sufficient capital in the public and/or private markets; or
- respond effectively to competitive pressures.

DiamiR's ability to generate revenue and achieve profitability is dependent on its ability to complete the development of its product candidates, obtain necessary regulatory approvals, and have its products under development manufactured and successfully marketed, of which there can be no guarantee. Although DiamiR has received revenue in the past from providing testing services to life sciences companies, and may again in the future, DiamiR cannot be certain that such services will bring sufficient revenue to support its operation and R&D. Thus, DiamiR may not be able to generate a profit until its product candidates become profitable.

The ongoing uncertainty in global economic conditions may negatively impact DiamiR's business, operating results or financial condition.

The continuing unfavorable global economic conditions and uncertainty have caused a general tightening in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy and extreme volatility in credit, equity and fixed income markets. These macroeconomic conditions could negatively affect DiamiR's business, operating results or financial condition in a number of ways. For example, potential future clients may be unable to fund purchases of products and services, which could cause them to delay, decrease or cancel purchases of DiamiR's products and services or to not pay DiamiR or to delay paying DiamiR for previously purchased products and services. DiamiR's clients may cease business operations or conduct business on a greatly reduced basis.

DiamiR faces significant, evolving competition which, if it fails to properly address, could adversely affect its business, results of operations, and financial condition.

The markets for molecular diagnostics are intensely competitive, and DiamiR faces significant competition from a number of different sources. Several of DiamiR's competitors have substantially greater name recognition and financial, technical, product development and marketing resources than DiamiR does. There has been significant merger and acquisition activity among a number of its competitors in recent years. Transaction induced pressures, or other related factors may result in negative market dynamics that could adversely affect DiamiR's business, results of operations and financial condition.

DiamiR competes in all of its markets with other major molecular diagnostics companies. Competitive pressures and other factors, such as new product introductions by DiamiR or its competitors, may result in price or market share erosion that could adversely affect its business, results of operations and financial condition. Also, there can be no assurance that DiamiR's products will achieve broad market acceptance or will successfully compete with other similar products available in the market.

DiamiR may engage in future acquisitions, which may be expensive and time consuming and from which it may not realize anticipated benefits.

DiamiR may acquire additional businesses, technologies, and products if DiamiR determines that these additional businesses, technologies, and products are likely to serve its strategic goals. The specific risks DiamiR may encounter in these types of transactions include but are not limited to the following:

- potentially dilutive issuances of its securities, the incurrence of debt and contingent liabilities and amortization expenses related to intangible assets with indefinite useful lives, which could adversely affect its results of operations and financial condition;
- using cash as acquisition currency may adversely affect interest or investment income, which may in turn adversely affect its earnings and/or earnings per share;
- difficulty in fully or effectively integrating any acquired technologies or software products into its current products and technologies, which would prevent DiamiR from realizing the intended benefits of the acquisition;
- difficulty in predicting and responding to issues related to product transition such as development, distribution and client support;
- the possible adverse effect of such acquisitions on existing relationships with third party partners and suppliers of technologies and services;
- the possibility that staff or clients of the acquired company might not accept new ownership and may transition to different technologies or attempt to renegotiate contract terms or relationships, including maintenance or support agreements;
- the possibility that the due diligence process in any such acquisition may not completely identify material issues associated with product quality, product architecture, product development, intellectual property issues, key personnel issues or legal and financial contingencies, including any deficiencies in internal controls and procedures and the costs associated with remedying such deficiencies;
- difficulty in entering geographic and business markets in which DiamiR has no or limited prior experience;
- difficulty in integrating acquired operations due to geographical distance and language and cultural differences; and
- the possibility that acquired assets become impaired, requiring DiamiR to take a charge to earnings which could be significant.

A failure to successfully integrate acquired businesses or technology could, for any of these reasons, have an adverse effect on DiamiR's financial condition and results of operations.

DiamiR's operations are dependent upon its key personnel. If such personnel were to leave unexpectedly, DiamiR may not be able to execute its business plan.

DiamiR's future performance depends in significant part upon the continued service of its key scientists and senior management personnel, many of whom have been with it for a significant period of time. These personnel have acquired specialized knowledge and skills with respect to DiamiR's business. Because at the time of this filing DiamiR has have 4 full-time employees and 3 part-time employees, DiamiR believes that it has a relatively small number of employees when compared to other leading companies in its industry, its dependence on maintaining its relationships with key employees is particularly significant. DiamiR is also dependent on its ability to attract high quality personnel, particularly in the areas of sales and applications development.

The industry in which DiamiR operates is characterized by a high level of employee mobility and aggressive recruiting of skilled personnel. There can be no assurance that DiamiR's current employees will continue to work for it. Loss of services of key employees could have an adverse effect on DiamiR's business, results of operations and financial condition. Furthermore, DiamiR may need to grant additional equity incentives to key employees and provide other forms of incentive compensation to attract and retain such key personnel. Equity incentives may be dilutive to DiamiR's per share financial performance. Failure to provide such types of incentive compensation could jeopardize DiamiR's recruitment and retention capabilities.

DiamiR has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of its financial statements, and have other adverse consequences.

DiamiR is a private company with limited accounting personnel and other resources with which to address its internal controls and procedures. It believes its current systems and internal controls are sufficient to ensure that its financial reporting is accurate at this stage of its operations.

In connection with the audits of DiamiR's financial statements for the years ended May 31, 2026 and 2025, material weaknesses in its internal control over financial reporting were identified in relation to its lack of in-house expertise related to U.S. GAAP, as well as the absence of comprehensive written control policies, or an internal audit function to ensure its internal controls are properly designed and implemented. There is also a lack of segregation of duties in financial reporting, and DiamiR does not have an audit committee. These material weaknesses are due to DiamiR's lack of working capital to hire additional staff. At its present state of development, DiamiR currently lacks the resources necessary to put in place such controls and procedures or to effectively monitor certain functions related to its controls and procedures. To date, DiamiR has relied on third-party consultants to supplement its financial reporting and controls and procedures.

Given that DiamiR has been operating as a private company, it did not have the necessary formalized processes to effectively implement review controls within its internal control over financial reporting.

If DiamiR fails to implement any required improvements to address any material weaknesses in its internal control over financial reporting, such material weaknesses could result in inaccuracies in its financial statements and could also impair its ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis.

The elimination of personal liability against DiamiR's directors and officers under Delaware law and the existence of indemnification rights held by its directors, officers and employees may result in substantial expenses.

DiamiR's bylaws ("Bylaws") provides that it is obligated to indemnify each of its directors or officers to the fullest extent authorized by Delaware law. Those indemnification obligations could expose DiamiR to substantial expenditures to cover the cost of settlement or damage awards against its directors or officers, which it may be unable to afford. Further, those provisions and resulting costs may discourage DiamiR or its stockholders from bringing a lawsuit against any of its current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit its stockholders.

DiamiR's information technology systems or data, or those of DiamiR's service providers or customers or users could be subject to cyber-attacks or other security incidents, which could result in data breaches, intellectual property theft, claims, litigation, regulatory investigations, significant liability, reputational damage and other adverse consequences.

DiamiR continues to expand its information technology (or IT) systems as its operations grow, such as product data management, procurement, inventory management, production planning and execution, sales, service and logistics, dealer management, financial, tax and regulatory compliance systems. This includes the implementation of new internally developed systems and the deployment of such systems in the U.S. and abroad. While, DiamiR maintains information technology measures designed to protect it against intellectual property theft, data breaches, sabotage and other external or internal cyber-attacks or misappropriation, its systems and those of their service providers are potentially vulnerable to malware, ransomware, viruses, denial-of-service attacks, phishing attacks, social engineering, computer hacking, unauthorized access, exploitation of bugs, defects and vulnerabilities, breakdowns, damage, interruptions, system malfunctions, power outages, terrorism, acts of vandalism, security breaches, security incidents, inadvertent or intentional actions by employees or other third parties, and other cyber-attacks.

To the extent any security incident results in unauthorized access or damage to or acquisition, use, corruption, loss, destruction, alteration or dissemination of DiamiR's data, including intellectual property and personal information, or DiamiR's products, or for it to be believed or reported that any of these occurred, it could disrupt DiamiR's business, harm its reputation, compel it to comply with applicable data breach notification laws, subject it to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require it to verify the correctness of database contents, or otherwise subject it to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to DiamiR and result in significant legal and financial exposure and/or reputational harm.

DiamiR also relies on service providers, and similar incidents relating to their information technology systems could also have a material adverse effect on DiamiR's business. There have been and may continue to be significant supply chain attacks. DiamiR's service providers, including its workforce management software provider, have been subject to ransomware and other security incidents, and DiamiR cannot guarantee that it or its service providers' systems have not been breached or that they do not contain exploitable defects, bugs, or vulnerabilities that could result in a security incident, or other disruption to, it or its service providers' systems. DiamiR's ability to monitor its service providers' security measures is limited, and, in any event, malicious third parties may be able to circumvent those security measures.

Further, the implementation, maintenance, segregation and improvement of these systems require significant management time, support and cost, and there are inherent risks associated with developing, improving and expanding its core systems as well as implementing new systems and updating current systems, including disruptions to the related areas of business operation. These risks may affect DiamiR's ability to manage its data and inventory, procure parts or supplies or manufacture, sell, deliver and service products, adequately protect its intellectual property or achieve and maintain compliance with, or realize available benefits under, tax laws and other applicable regulations.

Moreover, if DiamiR does not successfully implement, maintain or expand these systems as planned, DiamiR's operations may be disrupted, its ability to accurately and/or timely report its financial results could be impaired and deficiencies may arise in the Company's internal control over financial reporting (including with respect to DiamiR as a consolidated subsidiary), which may impact the Company's ability to certify its financial results. Moreover, DiamiR's proprietary information, including intellectual property and personal information, could be compromised or misappropriated and its reputation may be adversely affected. If these systems or their functionality do not operate as DiamiR expects them to, DiamiR or the Company may be required to expend significant resources to make corrections or find alternative sources for performing these functions.

A cyber security incident could cause a violation of the Health Insurance Portability and Accountability Act (HIPAA) and/or state consumer privacy laws, breach of customer and patient privacy, or other negative impacts.

DiamiR relies on its IT systems to manage scheduling and financial data, communicate with biopharma companies, including existing and prospective customers of DiamiR's testing services, vendors, and other third parties, and summarize and analyze operating results. In addition, DiamiR has made investments in technology, including the engagement of a third-party IT provider. A cyber-attack that bypasses DiamiR's IT security systems could cause an IT security breach, a loss of protected health information, or other data subject to privacy laws, a loss of proprietary business information, or a material disruption of DiamiR's IT business systems. This in turn could have a material adverse impact on DiamiR's business and result of operations. In addition, DiamiR's future results of operations, as well as its reputation, could be adversely impacted by theft, destruction, loss, or misappropriation of public health information, other confidential data, or proprietary business information.

Computer malware, viruses, and hacking and phishing attacks by third parties have become more prevalent in our industry and may occur on DiamiR's systems in the future. Because techniques used to obtain unauthorized access to or sabotage systems change frequently and generally are not recognized until successfully launched against a target, DiamiR and, by extension, the Company may be unable to anticipate these techniques or to implement adequate preventative measures. As cyber-security threats develop and grow, it may be necessary to make significant further investments to protect data and infrastructure. If an actual or perceived breach of security occurs, (i) DiamiR could suffer severe reputational damage adversely affecting customer or investor confidence, (ii) the market perception of the effectiveness of DiamiR's security measures could be harmed, (iii) DiamiR could lose potential sales and existing customers, its ability to deliver its services or operate its business may be impaired, (iv) DiamiR may be subject to litigation or regulatory investigations or orders, and (v) DiamiR may incur significant liabilities. DiamiR's insurance coverage may not be adequate to cover the potentially significant losses that may result from security breaches.

Risks Related to DiamiR's Products and Service

If researchers, clinicians and healthcare administrators do not adopt DiamiR's screening and diagnostic products, it will not achieve future sales growth.

DiamiR's business model is heavily reliant on the adoption of its products by researchers, clinicians, and healthcare administrators ("Industry Advocates"). These professionals play a critical role in the healthcare ecosystem, influencing both the acceptance and the utilization of new medical technologies. A failure to secure and maintain adoption among these groups poses a significant risk to DiamiR's operations. New products frequently are subject of slow adoption by healthcare specialists partly due to perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of DiamiR's future sales growth that it continues to work with key opinions leaders in the field, educate healthcare specialists about CogniMIR[®] and other assays in development, and demonstrate the clinical utility of its technology. If Industry Advocates do not believe in DiamiR's products, market acceptance of its products could fail to increase or could decrease, and its business could be harmed. Additionally, a lack of support from Industry Advocates could reduce the rate of coverage and reimbursement by both public and private third-party payors for DiamiR's products and services, which may further slow the market adoption of its product by physicians, significantly reduce its ability to achieve expected revenues and prevent it from becoming profitable. Slow adoption of DiamiR's products by Industry Advocates would significantly reduce its ability to achieve expected sales and could prevent it from achieving and maintaining profitability.

New product development and clinical validation involves a lengthy and complex process, and DiamiR may be unable to commercialize CogniMIR® or any other products it may develop on a timely basis, or at all.

It takes significant time to fully develop and commercialize CogniMIR® for risk of early neurodegeneration, and therefore its launch may be delayed or may not be successful. There can be no assurance that CogniMIR® will be successful in the risk assessment of Mild Cognitive Impairment and early Alzheimer's disease for a variety of technical and market reasons. DiamiR's other molecular diagnostic products, which are currently in various stages of early development, will take time to develop and commercialize, if it is able to commercialize them at all. Prior to commercializing any new products, DiamiR's will need to conduct substantial research and development, including validation studies. DiamiR's product development efforts involve a high degree of risk and may fail for many reasons, including failure to demonstrate the clinical utility of the product. As DiamiR develops products, it will have to make significant investments in product development and marketing resources. In addition, competitors may develop and commercialize competing products faster than DiamiR are able to do so. If DiamiR is unable to commercialize CogniMIR®, it may not be able to carry out its business.

DiamiR's research and development efforts will be hindered if it is not able to acquire or contract with third parties for access to additional plasma samples.

DiamiR's test development relies on its ability to secure access to independent cohorts of plasma samples and related clinical data. Many academic/research centers collect these samples for research purposes. In the past, DiamiR has been able to access these samples and relevant clinical outcomes (when available) through research collaborations/agreements. Some of these samples have been stored in -80c freezers and will be available to DiamiR when its clinical validation work begins. One of the key drivers of risk for any clinical study is access to samples.

DiamiR's studies focused on research, development and validation of its future products rely on access to single samples from multiple donors as well as multiple samples from the same donor over a period of time. Furthermore, DiamiR seeks access not only to archived samples but also to samples collected in prospective studies, which take a long time. Negotiating access to archived and prospectively collected donor samples and clinical data is typically a lengthy process involving several parties and approvals necessary to resolve complex issues such as research objectives and parameters, institutional review board approval, donor consent and privacy rights, publication rights, and intellectual property ownership. If DiamiR is not able to acquire or negotiate access to archived and prospectively collected donor plasma samples and related clinical data with source organizations, or if its competitors secure access to these samples before DiamiR, its ability to conduct studies to develop, validate and commercialize future tests will be limited or delayed. However, DiamiR believes that having frozen samples in its freezers reduces the risk of prolonged study timelines and allows DiamiR to more accurately estimate the number of samples in its study and to power the study accordingly.

DiamiR relies on a sole supplier for some of the materials used in its tests and services, and it may not be able to find replacements or transition to alternative suppliers in a timely manner.

DiamiR relies on different sole suppliers for certain materials, kits and supplies that it uses to perform its tests and services for its diagnostic tests. For example, DiamiR relies on Qiagen GmbH for its qPCR reagents and plates. DiamiR does not maintain an agreement with Qiagen GmbH; their reagents are readily available for purchase, additionally, the volume of DiamiR's business is not material to them. In addition to Qiagen, DiamiR works with other multinational stable corporations for its supplies. Although DiamiR does not currently have any agreements with other suppliers and technologies, it believes other providers, such as ThermoFisher, which offers the TaqMan qPCR kits are easily accessible and it can quickly begin working with them, if necessary. At the time of this filing all other reagents DiamiR uses are commonly available through multiple vendors on similar terms.

From time to time, DiamiR also may purchase other reagents used in its tests and services from sole-source suppliers. While it may develop alternate sourcing strategies for these materials and vendors, DiamiR cannot be certain whether these strategies will be effective, or the alternative sources will be available in a timely manner. If these suppliers can no longer provide DiamiR with the supplies, DiamiR needs to perform its tests and services, if the materials do not meet its quality specifications, or if DiamiR cannot obtain acceptable substitute materials, an interruption in test processing and services could occur. Any such interruption may directly impact DiamiR's revenue and cause it to incur higher costs.

If DiamiR cannot enter into and maintain new clinical collaborations, its efforts to commercialize CogniMIR® and its development of other products could be delayed.

DiamiR currently has several ongoing collaborations with highly regarded academic institutions in the NDs field. DiamiR's success in the future may depend in part on its ability to enter into agreements with other leading institutions in the NDs field. In the process of seeking clinical collaborations in the future DiamiR expects to engage in discussions with third parties, which may or may not lead to collaborations.

If DiamiR's clinical tests do not perform as expected in its validation studies, it may not be able to achieve widespread market adoption among physicians, which would cause its operating results, reputation, and business to suffer.

There is no guarantee that the accuracy and reproducibility DiamiR has demonstrated to date will continue in its planned clinical validation studies. As a result, the failure of its products to perform as expected would significantly impair its operating results and its reputation. DiamiR may be subject to legal claims arising from any defects or errors in its clinical services tests.

DiamiR's ability to commercialize the diagnostic products that it develops is dependent on its relationships with laboratory services providers and support of its products.

DiamiR relies on third-party providers to draw the donor blood samples and prepare plasma in accordance with its protocol. DiamiR's business will suffer if these service providers do not support CogniMIR® or the other products that it may develop. A lack of acceptance of its products by these service providers could result in lower test volume. DiamiR's business may suffer from the repetition of the process and increased costs.

DiamiR may use third party collaborators to help it develop, validate, or commercialize any new products, and its ability to commercialize such products could be impaired or delayed if these collaborations are unsuccessful.

DiamiR may pursue strategic collaborations for the development, validation, and commercialization of any new diagnostic products it may develop. In any future third party collaboration, DiamiR may be dependent upon its collaborators performing their responsibilities and their cooperation. DiamiR cannot control the amount of time and effort its collaborators will devote to performing their responsibilities under DiamiR's agreements with them. The development, validation and commercialization of its potential products may be delayed if collaborators fail to fulfill their responsibilities in a timely manner or in accordance with regulatory requirements or if they breach or terminate their collaboration agreements with DiamiR. In addition, a failure by third parties to perform their obligations in compliance with regulatory requirements may cause DiamiR's development, validation, or commercialization of new products to fail to meet regulatory requirements, which may require it to repeat the process. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, DiamiR may be unable to obtain regulatory approval for or commercialize its future products. Furthermore, disputes with its collaborators could also impair DiamiR's reputation or result in development delays, decreased revenues and litigation expenses.

If DiamiR cannot enter into new clinical study collaborations, its product development and subsequent commercialization could be delayed.

Historically, DiamiR has entered into clinical study collaborations with academic and medical institutions for access to clinical samples and expertise related to its tests and services, and its success in the future depends in part on its ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations, and on occasion DiamiR key contact may leave the organization. Some organizations may limit the number of collaborations they have with any one company, so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaboration with many companies at once, which can extend the time it takes to develop, negotiate, and implement a collaboration. Moreover, it may take longer to obtain the samples DiamiR needs which could delay its trials, publications, and product launches and reimbursement. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for its diagnostic tests, and its inability to control when and if results are published may delay or limit its ability to derive sufficient revenue from them.

If DiamiR is unable to identify collaborators willing to work with it to conduct clinical utility studies, or the results of those studies do not demonstrate that a molecular diagnostic test do not impact patient treatment or physician behavior, commercial adoption of such test may be slow, which would negatively impact its business.

Clinical utility studies are designed to show the impact of the molecular diagnostic test results on patient care and management. Clinical utility studies are typically performed with collaborating physicians at medical centers and hospitals, and generally result in peer-reviewed publications. Sales and marketing representatives use these publications to demonstrate to customers how to use a molecular diagnostic clinical test, as well as why they should use it. These publications are also used with payers to obtain coverage for a molecular diagnostic test, helping to assure there is appropriate reimbursement. DiamiR will need to conduct additional studies for its molecular diagnostic tests and other diagnostic tests it plans to introduce, to increase the market adoption and obtain coverage and adequate reimbursement. Should DiamiR not be able to perform these studies, should the costs or length of time required for these studies exceed their value, or should their results not provide clinically meaningful data and value for oncologists and other physicians, adoption of its molecular diagnostic tests could be impaired, and DiamiR may not be able to obtain coverage and adequate reimbursement for them.

In the future, DiamiR may rely on third parties to process and transmit claims to payers for its clinical services, and any delay in processing or transmitting could have an adverse effect on its revenue and financial condition.

As part of its future commercialization efforts, DiamiR may hire third parties to provide overall processing of claims and to transmit actual claims to payers based on specific payer billing formats. If claims for its clinical services are not submitted to payers on a timely basis, or if DiamiR is again required to switch to a different third-party processor to handle claim submissions, DiamiR may experience delays in its ability to process claims and receive payment from payers, which could have a material adverse effect on its business, financial condition and results of operations.

DiamiR recognizes that there are inherent risks associated with third-party relationships, which may adversely affect its business.

DiamiR expects to continue to depend on third-party service providers for the foreseeable future, but DiamiR recognizes that there are inherent risks associated with these third-party relationships. For example, its reputation may be harmed by allegations of wrong-doings or violations of regulations by the third-party service providers. The security of its confidential and sensitive business information may be breached if the third-party service providers do not exercise high standard of care to guard and protect the information that comes to their possession because of their relationships with DiamiR. DiamiR does not have control over the amount of time and effort and level of care its third-party service providers will devote to performing their responsibilities under DiamiR's agreements with them.

If DiamiR is unable to use or maintain its trademarks and trade names or build brand recognition in its markets of interest, its business may be adversely affected.

DiamiR's US Federal trademarks for the marks CogniMIR® and DiamiR® have been registered by the USPTO. If DiamiR does not maintain any registrations granted by the USPTO, DiamiR may encounter difficulty in continuing to use or enforce such trademarks. DiamiR's trademarks or trade names may be challenged, infringed, circumvented, declared generic/descriptive or determined to be infringing on other marks. As a means to enforce its trademark rights and prevent infringement/dilution, DiamiR may be required to file trademark claims against third parties or initiate trademark opposition/cancellation proceedings. This can be expensive and time-consuming. In addition, a third party could file trademark claims against DiamiR or the Company, leading a court to decide that one or more of DiamiR's trademarks is not valid or unenforceable and enjoin DiamiR from further use of the same. If DiamiR is unable to use or maintain its company marks for purposes of building brand recognition by potential partners or customers or DiamiR is unable to establish brand recognition based on those trademarks and trade names, then it may not be able to compete effectively, and DiamiR's business may be adversely affected.

DiamiR may be unable to develop new products and services or acquire products and services on favorable terms.

The molecular diagnostics industry is characterized by ongoing technological developments and changing customer requirements. As such, DiamiR's results of operations and continued growth depend, in part, on its ability in a timely manner to develop or acquire rights to, and successfully introduce into the marketplace, enhancements of existing products and services or new products and services that incorporate technological advances, meet customer requirements, and respond to products developed by DiamiR's competition. DiamiR cannot provide any assurance that it will be successful in developing or acquiring such rights to products and services on a timely basis, or that such products and services will adequately address the changing needs of the marketplace, either of which could adversely affect DiamiR's results of operations.

In addition, DiamiR must regularly allocate considerable resources to research and development of new products, services and technologies. The research and development process generally takes a significant amount of time from design stage to product launch. This process is conducted in various stages. During each stage, there is a risk that DiamiR will not achieve its goals on a timely basis, or at all, and DiamiR may have to abandon a product in which DiamiR has invested substantial resources.

If DiamiR's laboratory becomes inoperable for any reason, DiamiR will be unable to perform its testing and its business will be harmed.

The laboratory and equipment DiamiR uses to perform its tests and services would be costly to replace and could require substantial lead time to replace and qualify for use if they became inoperable. DiamiR's facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, power outages, and health epidemics or pandemics, including the outbreak of Coronavirus (COVID-19), which may render it difficult or impossible for DiamiR to perform its testing or services for some period of time, or to receive and store samples. The inability to perform its tests or services for even a short period of time, including due to disruption in staffing, supplies, distribution, or transport or temporary closures related to an outbreak of disease such as COVID-19, may result in the loss of customers or harm its reputation, and DiamiR may be unable to regain those customers in the future.

If DiamiR's landlord does not renew its lease, its clinical and testing operations will be halted until DiamiR locates and sets up a new laboratory.

DiamiR currently has a one year lease ending in December 2025, with an option to extend by an additional year, for its laboratory space. DiamiR cannot guarantee that in the future, its landlord will extend its lease. DiamiR cannot be confident that it will find appropriately sized space in and around New Haven, CT, nor can DiamiR be confident that any new Lab space will be cost effective. There is an inherent risk of losing key employees if DiamiR is forced to move its Laboratory operation into a new space.

If DiamiR's information technology or communications systems fail or DiamiR experiences a significant interruption in their operation, its reputation, business and results of operations could be materially and adversely affected.

The efficient operation of DiamiR's business is dependent on its information technology and communications systems. The failure of these systems to operate as anticipated could disrupt its business and result in decreased revenue and increased overhead costs. In addition, DiamiR does not have complete redundancy for all of its systems and its disaster recovery planning cannot account for all eventualities. DiamiR's information technology and communications systems, including the information technology systems and services that are maintained by third party vendors, are vulnerable to damage or interruption from natural disasters, fire, terrorist attacks, epidemics, pandemics including COVID-19, malicious attacks by computer viruses or hackers, power loss, failure of computer systems, Internet, telecommunications or data networks. Additionally, its future clinical services will be largely dependent on its internally developed Laboratory Information Management System or LIMS, which is its automated basis of managing operations and storing data and customer information. This LIMS was developed to meet its CLIA/CAP regulatory requirements and was reviewed as part of its most recent CLIA inspection in 2023, which DiamiR passed. Currently the LIM System is fully operational. If these systems or services become unavailable or suffer a security breach, or are uneconomical or impossible to update and modify, DiamiR may expend significant resources to address these problems, and its reputation, business and results of operations could be materially and adversely affected.

Risks Related to Regulation Affecting DiamiR

DiamiR may now or in the future be subject to laws and regulations relating to laboratory testing, which could materially adversely impact its ability to offer its products or services.

The clinical laboratory testing sector is highly regulated in the United States. DiamiR's Laboratory is subject to and operated under CLIA regulation (CLIA ID number (07D1091103)); DiamiR also has active accreditation from The College of American Pathologists (CAP Number 7215351) for the Laboratory. CLIA is a federal law (administered by the Centers for Medicare & Medicaid Services, or CMS) that, in partnership with the states, regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease or impairment of, or assessment of the health of, human beings. CLIA regulations require clinical laboratories to obtain a certificate commensurate with the type of testing being performed and mandate specific standards in areas including personnel qualifications, administration, participation in proficiency testing, patient test management and quality assurance. CLIA certificates must be renewed every two years, and renewal requires undergoing survey and inspection. CLIA and/or state inspectors may conduct random inspections or conduct inspections as a result of a complaint or reported incident.

miRNA profiling of biospecimens will be performed at its Laboratory. The failure of DiamiR to maintain its CLIA certification or accreditation appropriate to the type of testing DiamiR performs, or to comply with CLIA regulations or applicable state licensure requirements could result in adverse regulatory action that, if not timely corrected, could result in DiamiR being unable to continue offering its testing services, which could adversely affect its business. Similarly, if DiamiR does not hold state permits or licenses in those states that require them, it may limit its ability to offer its products and services on a national basis.

Maintaining adequate sales of DiamiR's product, if any of its product candidates are approved, may depend on the availability of adequate reimbursement to its customers from third-party payers, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs.

Maintaining and growing sales of its approved products depends in part on the availability of adequate coverage and reimbursement of its products by third-party payers, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Hospitals, clinical laboratories and other healthcare provider customers that may purchase its products generally bill various third-party payers to reimburse all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of its products. DiamiR's customers' access to adequate reimbursement by government and private insurance plans is central to the acceptance of its products. DiamiR may be unable to monetize its commercial products on a profitable basis if third-party payers refuse to cover its products or pay DiamiR low levels of reimbursement, or if its costs of production increases faster than increases in reimbursement levels.

Additionally, third-party payers are increasingly reducing reimbursement for medical products and services. In addition, the U.S. government, state legislatures, and foreign governments have and may continue to implement cost-containment measures and more restrictive policies, including price controls and restrictions on reimbursement. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Further, the Budget Control Act of 2011 (the "Budget Control Act") established a process to reduce federal budget deficits through an automatic "sequestration" process if deficit reductions targets are not otherwise reached. Under the terms of the Budget Control Act, sequestration imposes cuts to a wide range of federal programs, including Medicare, which is subject to a two percent cut. The Bipartisan Budget Act of 2013 extended the two percent sequestration cut for Medicare through fiscal year 2023, and a bill signed by President Obama on February 15, 2014 further extended this cut for an additional year, through fiscal year 2024. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into law in March 2020, included critical relief from sequestration cuts as it applies to Medicare payments, exempting Medicare from the effects of sequestration from May 1, 2020, through March 31, 2022. Cuts of 1% were imposed from April 1 through June 30, 2022. As of July 1, 2022, cuts of two percent were reimposed and are set to remain in effect until 2031 unless additional Congressional action is taken. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year.

While DiamiR cannot predict whether third-party reimbursement to its customers will be adequate, cost-containment measures and similar efforts by third-party payers, including government programs such as Medicare and Medicaid, could substantially impact the sales of its products and potentially limit its net revenue and results.

If any of its product candidates are approved, DiamiR may be adversely affected by healthcare policy changes, including additional healthcare reform and changes in managed healthcare.

Healthcare reform and the growth of managed care organizations have been considerable forces in the medical diagnostics industry and in recent political discussions. These forces have placed, and are expected to continue to place, constraints on the levels of overall pricing for healthcare products and services as well as the coverage available by public and private insurance and thus, could have a material adverse effect on the future profit margins of its products or the amounts that DiamiR are able to receive from third parties for the licensing of its products. Changes in the United States healthcare market could also force DiamiR to alter its approach to selling, marketing, distributing and servicing its products and customer base. In and outside the United States, changes to government reimbursement policies could reduce the funding that healthcare service providers have available for diagnostic product expenditures, which could have a material adverse impact on the use of the products DiamiR are developing and its future sales, license and royalty fees and profit margin.

For example, the ACA requires CMS to reduce payments to hospitals reimbursed under Medicare's Inpatient Prospective Payment System ("IPPS") that have higher than expected readmissions. This and other applicable requirements set forth under the ACA and its current and future implementing regulations may significantly increase its costs, and/or reduce its customer's ability to obtain adequate reimbursement for tests performed with its products, which could adversely affect its business and financial condition. In addition to direct impacts from reimbursement cuts, revenue from its products could be negatively impacted if reimbursement cuts reduce microbiology budgets. While the ACA is intended to expand health insurance coverage to uninsured persons in the United States, other elements of the legislation, such as Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, and pilot programs to evaluate alternative payment methodologies, make it difficult to determine the overall impact on sales of its products. In addition to uncertainty regarding the impact of the implementation of the ACA, there have been a number of attempts to challenge the legality of the ACA. Most significantly, on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the law.

In recent years, other legislative, regulatory, and political changes aimed at regulating healthcare delivery in general and clinical laboratory tests in particular have been proposed and adopted in the United States. Reimbursement for the laboratory industry is under significant pressure. In January 2015, HHS announced a plan to shift the Medicare program and the healthcare system at large, toward paying providers based on quality, rather than the quantity of care provided to patients. In 2017, Medicare's clinical laboratory reimbursement system became tied to private market rates with the start of the effective period for the Protecting Access to Medicare Act of 2014 ("PAMA"), changing the payment environment for clinical laboratory tests. The measures implemented by PAMA and ACA regulations can result in reduced prices, added costs, and decreased test utilization for its customers, although the full impact on its business of the ACA, changes to the IPPS, PAMA, and other applicable laws, regulations, and policies is uncertain.

DiamiR cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which DiamiR may do business, or the effect of any future legislation or regulation will have on its industry generally, its ability to successfully commercialize its products, and its overall business operations. Continued changes in healthcare policy could substantially impact the volume and revenue of its tests, increase costs and divert management's attention from its business. For example, any expansion in the government's regulation of the United States healthcare system could result in decreased profits to DiamiR, lower reimbursements to its customers for laboratory testing or reduced medical procedure volumes.

The regulatory processes applicable to its products and operations are expensive, time-consuming, and uncertain and may prevent DiamiR from obtaining required authorizations for the commercialization of its products.

Within the laboratory, most tests can be divided into two categories: in vitro diagnostics (IVDs) and laboratory developed tests (LDTs). IVDs are commercially manufactured assays and make up the majority of clinical laboratory tests, such as those in a comprehensive metabolic panel (CMP) and a complete blood count (CBC). LDTs, on the other hand, are developed by individual laboratories and overseen by highly trained and qualified laboratory directors. In 1979, Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). These amendments gave FDA explicit authority to regulate medical devices. These included tests developed by manufacturers sold for commercial purposes to laboratories around the country. However, the amendments did not specifically include tests developed by laboratories for their own use. Then, in 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA). These gave clinical laboratories the ability to develop and perform their own tests to fill gaps in available testing and provided the framework for LDT regulation. Today, all laboratories must have appropriate CLIA accreditation, overseen by the Centers for Medicare and Medicaid Services (CMS), to perform LDTs. The regulatory agency oversees around 320,000 entities.

Historically, the FDA has exercised enforcement discretion for LDTs, allowing labs to offer tests with little input from the agency. On May 6, 2024, FDA released its long-awaited update to its LDT policy in the Federal Register. Under these new guidelines, the FDA will phase out enforcement discretion in 5 stages over 4 years allowing labs to adjust to these new requirements in a timely and orderly manner. While grandfathering marketed LDTs and creating a few other exceptions, the FDA will require all new LDTs to be launched according to its new guidelines.

On March 31, 2025, a Federal Judge struck down FDA's final rule that sought to regulate laboratory-developed tests (LDTs) as medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). The court ruled that the FDA lacked the statutory authority to classify LDTs — diagnostic tests developed and used within a single laboratory — as medical devices, emphasizing that LDTs are professional medical services, not tangible products subject to FDA regulation. This decision halts the FDA's plan to phase out its general enforcement discretion over LDTs, which would have introduced new compliance obligations over a four-year period. The court's ruling underscores that oversight of LDTs falls under the Clinical Laboratory Improvement Amendments (CLIA), administered by the Centers for Medicare & Medicaid Services (CMS), not the FDA.

The FDA announced in May 2025 that it will not appeal this decision. If the FDA changes its position on this appeal, and wins on appeal, risks associated with the new landscape of LDTs include but are not limited to:

- DiamiR's inability to implement quality standards included in the new guidelines
- DiamiR's inability to implement all FDA requirements for LDTs
- Backlog at the FDA for review of submission
- Additional regulations being adopted by the FDA
- Increased timeline to product launch, delaying revenue for the company
- Increased regulatory oversight resulting in delays for product launch
- Increased costs of product development and regulatory compliance

- Increase costs may arise from:
 - More expansive validation study design
 - Hiring additional regulatory compliance talent
 - Hiring additional statistical experts
 - Other unanticipated costs

Sales of its diagnostic product candidates outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. DiamiR may not be able to obtain foreign regulatory approvals on a timely basis or at all. Marketing authorization from the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing. Failure to comply with foreign regulatory requirements, or to obtain required clearances or approvals, could impair its ability to commercialize its diagnostic product candidates outside of the United States.

Global health crises may divert regulatory resources and attention away from approval processes for its products. This could materially lengthen the regulatory approval process of new products, which would delay expected commercialization of such new products.

DiamiR and their suppliers, contract manufacturers and customers are subject to various governmental laws and regulations, and DiamiR may incur significant expenses to comply with, and experience delays in DiamiR's product commercialization as a result of, these laws and regulations.

DiamiR's operations are affected by various state, federal, and international healthcare, environmental, anti-corruption, fraud and abuse (including anti-kickback and false claims laws), privacy, and employment laws as well as international political sanctions. Violations of these laws and sanctions can result in criminal or civil penalties, including substantial fines and, in some cases, exclusion from participation in federal health care programs such as Medicare and Medicaid. In some cases, the violation of such laws could potentially lead to individual liability and imprisonment.

DiamiR is also subject to regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Following the introduction of a product, these and other government agencies will periodically review DiamiR's manufacturing processes, product performance and compliance with applicable requirements.

DiamiR is also subject to various U.S. healthcare related laws regulating sales, contracting, marketing, and other business arrangements and the use and disclosure of individually identifiable health information. These include but are not limited to:

- The federal Anti-Kickback Statute, a criminal law, which prohibits persons and entities from knowingly and willfully offering, paying, providing, soliciting, or receiving any remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce or reward the referral of an individual, or the purchasing, leasing, ordering, recommending, furnishing or arranging for a good or service, for which payment may be made under a federal health care program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti-Kickback Statute can result in significant civil monetary penalties and criminal fines, as well as imprisonment and exclusion from participation in federal healthcare programs.
- The federal False Claims Act, which imposes significant civil penalties, treble damages and potential exclusion from participation in federal healthcare programs against any person or entity that, among other things, knowingly presents, or causes to be presented, to the federal government claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Further, a violation of the federal Anti-Kickback Statute can serve as a basis for liability under the federal civil False Claims Act. The qui tam provisions of the False Claims Act allow private individuals to bring actions on behalf of the federal government and to share in any monetary recovery. There is also the federal Criminal False Claims Act, which is similar to the federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government.

- The federal Stark law, which prohibits physicians from referring patients to receive “designated health services” payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. Violation of the federal Stark law can result in significant civil monetary penalties and exclusion from participation in the federal healthcare programs.
- The Eliminating Kickbacks in Recovery Act, which makes it a federal crime to knowingly and willfully solicit or receive any remuneration (including kickbacks, bribes, or rebates) in return for referring a patient to a recovery home, clinical treatment facility, or laboratory where the services are covered by a “health care benefit program,” which includes private payers, or pay or offer any remuneration to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory. Violations of the law may result in penalties per occurrence and imprisonment.
- Federal criminal statutes created by HIPAA impose criminal liability for, among other things, knowingly and willfully (i) executing (or attempting to execute) a scheme to defraud any health care benefit program, including private payers, or (ii) falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for items or services under a health care benefit program.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, which also restricts the use and disclosure of protected health information, mandates the adoption of standards relating to the privacy and security of protected health information, and requires us to report certain security breaches to health care provider customers with respect to such information where DiamiR is acting as a HIPAA business associate to that customer.
- The federal Physician Payment Sunshine Act, which requires applicable manufacturers of certain medical devices that may be reimbursed by Medicare, Medicaid, or the Children’s Health Insurance Program, among others, to annually track and report payments or other transfers of value provided to U.S. licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives, and U.S. teaching hospitals, as well as certain ownership and investment interest held in the manufacturer by physicians and their immediate family members.

Similar requirements have been adopted by many states and foreign countries. Violations of any of these laws can lead to additional legal risk such as risk of plaintiff class actions, state Attorney General actions, and investigations by the Federal Trade Commission, among others.

Failure to comply with applicable requirements, or later discovery of previously unknown problems with DiamiR’s products or manufacturing processes, including DiamiR’s failure or the failure of one of DiamiR’s contract manufacturers to take satisfactory corrective action in response to an adverse inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of DiamiR’s products;
- corrective field actions for DiamiR’s products;
- submission of reports to FDA or other regulatory authorities;
- total or partial suspension of production or distribution;

- withdrawal or suspension of marketing clearances or approvals;
- clinical holds for investigations;
- untitled letters or warning letters;
- refusal to permit the import or export of DiamiR's products;
- criminal prosecution; and
- exclusion or debarment from participation in federal health care programs such as Medicare and Medicaid.

Any of these actions, in combination or alone, could prevent DiamiR from marketing, distributing and selling DiamiR's products.

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by DiamiR. DiamiR believes that the FDA would request that DiamiR initiate a voluntary recall if a test was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could expose DiamiR to product liability or other claims (including contractual claims from parties to whom it sells products) and harm DiamiR's reputation with customers.

The use of DiamiR's diagnostic products by DiamiR's customers is also affected by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance, quality control and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories, hospitals, providers or other customers with laboratories from using some or all of DiamiR's diagnostic products.

If DiamiR fails to comply with federal, state and foreign laboratory licensing requirements, DiamiR could lose the ability to perform its tests or experience disruptions to its business.

DiamiR is subject to CLIA regulations, a federal law that regulates commercial clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or impairment of, or the assessment of the health of, human beings. CLIA regulations mandate specific personnel qualifications, facilities layout, quality systems, inspections and proficiency testing. CLIA certification is also required in order for DiamiR to be eligible to bill federal and state healthcare programs (Medicare and Medicaid), as well as many private third-party payers, for its molecular diagnostic tests. To renew these certifications, DiamiR is subject to bi-annual inspections. Moreover, CLIA inspectors may make random inspections of its clinical laboratory. DiamiR is also required to maintain a CT State license to conduct testing in its New Haven, Connecticut laboratory. In addition, its laboratory is required to be licensed by certain states, including Pennsylvania, California, Maryland, New York and Rhode Island. New York law requires DiamiR to obtain test-specific approval before offering its tests as LDT. California, Maryland, New York and Rhode Island laws also mandate proficiency testing for laboratories licensed under the laws of each respective State regardless of whether such laboratories are located in California, Maryland, New York or Rhode Island. If DiamiR is unable to obtain or maintain its CLIA certificate for its laboratory, whether as a result of revocation, suspension or limitation, DiamiR would no longer be able to perform its current clinical services on samples from those States, which could have a material adverse effect on its business, financial condition and results of operations. If DiamiR were to lose its licenses issued by States where it is required to hold licenses, if such licenses expired or were not renewed, or if it failed to obtain and maintain a State license that it is required to hold, it may be subject to significant fines, penalties and liability, and may be forced to cease testing (if Connecticut) or cease testing specimens from those States (if California, New York, Maryland, or Rhode Island), which could have a material adverse effect on DiamiR's business, financial condition and results of operations. New molecular diagnostic tests DiamiR may develop may be subject to new requirements by governmental bodies, including state governments, and DiamiR may not be able to offer its new molecular diagnostic tests in such jurisdictions until such requirements are met.

Risks Related to DiamiR's Intellectual Property and Product Liability

DiamiR may be unable to protect or obtain proprietary rights.

In developing, manufacturing and using its products, DiamiR employs a variety of proprietary and patented technologies. DiamiR cannot provide any assurance that the patent and pending patent applications that it currently owns provide (or will provide when issued) protection from competitive threats or from patent challenges. In addition, DiamiR cannot provide any assurances that it will be successful in obtaining and maintaining its patents or in obtaining licenses to proprietary or patented technologies of others in the future.

Furthermore, effective intellectual property protection may not be available in every country in which DiamiR operates or intends to operate its business in. There can be no assurance that others will not offer technologies, functions, features, or concepts that are substantially similar to DiamiR's and compete with DiamiR's business, or copy or otherwise obtain, disclose and/or use DiamiR's brand, platform features, design elements, DiamiR's algorithms and capabilities or other information that DiamiR considers proprietary without authorization. DiamiR may be unable to prevent third parties from seeking to register, acquire, or otherwise obtain trademarks, copyrights or domain names that are similar to, infringe upon or diminish the value of its trademarks, copyrights, and its other proprietary rights. Third parties may obtain or misappropriate certain of its data through website scraping, robots, or other means to launch copycat sites, aggregate its data for their internal use, or to feature or provide its data through their respective websites, and/or launch businesses monetizing this data. While DiamiR routinely employs technological and legal measures in an attempt to divert, halt, or mitigate such operations, it may not always be able to detect or halt the underlying activities as technologies used to accomplish these operations continue to rapidly evolve.

If the protection of its proprietary rights and data is inadequate to prevent unauthorized use or misappropriation by third parties, the value of its brand and other intangible assets may be diminished and its competitors may be able to more effectively mimic its technologies, offerings, or features or methods of operations. Even if DiamiR does detect violations or misappropriations and decide to enforce its rights, litigation that may be necessary to enforce its rights may not be pursued by DiamiR, as it may be time-consuming and expensive, and divert its management's attention. Additionally, a court of a competent jurisdiction may determine that certain of DiamiR's intellectual property rights are unenforceable. If DiamiR fails to protect its intellectual property and data in a cost-effective and meaningful manner, its competitive standing could be harmed and the brand, reputation, business, results of operations, and financial condition could be materially adversely affected.

Intellectual Property infringement claims by other companies could result in costly disputes and could limit DiamiR's ability to sell its products.

Litigation over intellectual property is prevalent in the molecular diagnostics industry. As the market for molecular diagnostics continues to grow and the number of participants in the market increases, DiamiR may increasingly be subject to patent infringement claims. While DiamiR may attempt to obtain licenses to such patents, DiamiR may be unable to do so on favorable terms, or at all. Additionally, if its products are found to infringe third-party patents, DiamiR may be required to pay damages and/or lose the ability to sell certain products, causing its revenues to decrease or causing damage to DiamiR's reputation in the industry also leading to a material adverse effect on DiamiR's business.

If product liability lawsuits are successfully brought against DiamiR, DiamiR may incur substantial liabilities and may have to limit or cease sales of its products.

The testing, manufacturing, and marketing of medical diagnostic products involves an inherent risk of product liability claims. If DiamiR cannot successfully defend itself against product liability claims, DiamiR may incur substantial liabilities or be required to limit or cease sales of its products. In addition, a defect in the design or manufacture of DiamiR's products could have a material adverse effect on DiamiR's reputation in the industry and subject DiamiR to claims of liability for injury and otherwise. Any substantial loss resulting from such a claim could have a material adverse effect on DiamiR's profitability and the damage to DiamiR's reputation in the industry could have a material adverse effect on DiamiR's business.

SELECTED FINANCIAL DATA

AS REPORTED

	Year Ended December 31.	
	2025	2024
Net loss available to common shareholders	\$ (1,363,270)	\$ (4,267,806)
Net loss per common share, basic and diluted	\$ (0.19)	\$ (0.78)
Weighted average common shares outstanding, basic and diluted	7,351,784	5,453,103
Common shares outstanding at year end	8,143,757	5,608,757

	Six Months Ended June 30,	
	2026	2025
	(Unaudited)	(Unaudited)
Net loss available to common shareholders	\$ (1,326,004)	\$ (441,780)
Net loss per common share, basic and diluted	\$ (1.6)	\$ (0.6)
Weighted average common shares outstanding, basic and diluted ⁽¹⁾	814,375	712,679
Common shares outstanding at period end ⁽¹⁾	814,375	714,375

AS ADJUSTED FOR 1-FOR-10 REVERSE STOCK SPLIT (unaudited)

	Year Ended December 31.	
	2025	2024
	(Unaudited)	(Unaudited)
Net loss available to common shareholders	\$ (1,363,270)	\$ (4,267,806)
Net loss per common share, basic and diluted	\$ (1.9)	\$ (7.8)
Weighted average common shares outstanding, basic and diluted ⁽¹⁾	735,178	545,310
Common shares outstanding at year end ⁽¹⁾	814,375	560,875

	Six Months Ended June 30,	
	2026	2025
	(Unaudited)	(Unaudited)
Net loss available to common shareholders	\$ (1,326,004)	\$ (441,780)
Net loss per common share, basic and diluted	\$ (1.6)	\$ (0.6)
Weighted average common shares outstanding, basic and diluted ⁽¹⁾	814,375	712,679
Common shares outstanding at period end ⁽¹⁾	814,375	714,375

(1) All per share amounts and shares outstanding for all periods have been retroactively restated to reflect the company's 1 for 10 reverse stock split, which was effective on July 20, 2026.

USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus for general corporate purposes, including for general working capital purposes, which may include the repayment of outstanding debt.

DILUTION

If required, we will set forth in a prospectus supplement the following information regarding any material dilution of the equity interests of investors purchasing securities in an offering under this prospectus:

- the net tangible book value per share of our equity securities before and after the offering;
- the amount of the increase in such net tangible book value per share attributable to the cash payments made by purchasers in the offering; and
- the amount of the immediate dilution from the public offering price which will be absorbed by such purchasers.

DESCRIPTION OF SECURITIES

We are authorized to issue 160,000,000 shares of capital stock consisting of preferred stock and common stock. Below is a summary of the material terms of each such class.

As of the date hereof, there were 2,938,625 shares of our Common Stock and 179,693 shares of Series A Preferred Stock issued and outstanding, respectively.

Common Stock

The Corporation is authorized to issue 150,000,000 shares of common stock, with a par value of \$0.0001 per share ("Common Stock").

Voting rights. Each holder of Common Stock is entitled to one vote for each share of Common Stock held of record by such holder on all matters voted upon by the Company's stockholders, provided, however, that, except as otherwise required in the Charter, as provided by law or by the resolution(s) or any certificate of designation providing for the issue of any preferred stock, the holders of Common Stock are not entitled to vote on any amendment to the Charter that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Charter (including any certificate of designation relating to any series of preferred stock) or pursuant to the DGCL.

Dividend rights. Subject to the rights of holders of preferred stock, holders of Common Stock are entitled to receive ratably, on a per share basis, dividends and other distributions in cash, stock or property of the Company as may be declared and paid from time to time by the Company's board of directors (the "Board") out of any of the Company's assets legally available therefor.

Rights upon liquidation. Subject to applicable law and the rights of holders of preferred stock, holders of Common Stock shall be entitled to receive ratably the assets and funds of the Company available for distribution in the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, unless disparate or different treatment of the shares of each such class with respect to distributions upon any such liquidation, dissolution or winding up is approved in advance by holders of a majority of the outstanding shares of Common Stock.

Other rights. No holder of Common Stock is entitled to preemptive or subscription rights contained in the Charter or in the Bylaws. There are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences, and privileges of holders of the Common Stock are subject to those of the holders of any shares of the preferred stock that the Company may issue in the future.

Preferred Stock

The Corporation is authorized to issue 10,000,000 shares of Preferred Stock, with a par value of \$0.0001 per share (“Preferred Stock”). The Preferred Stock may be issued from time to time in one or more series. The board of directors of the Corporation is hereby expressly authorized, by resolution or resolutions thereof, to provide for the issuance of one or more series of Preferred Stock and, with respect to each such series, to fix the number of shares constituting such series and the designation, powers (including voting powers), preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof. The powers, preferences, and rights of each series of Preferred Stock may differ from those of any and all other series at any time outstanding. The Common Stock (as defined below) shall be subject to the express terms of the Preferred Stock and any series thereof.

The board of directors designated 1,810,000 shares of Preferred Stock as Series A Preferred Stock. The holders of Series A Preferred Stock do not have any voting rights and shares of Series A Preferred Stock are not convertible. The Series A Preferred Stock is not redeemable. Upon the completion of a distribution pursuant to a sale or other disposition of all or substantially all of our assets, certain mergers, consolidations and transfers of securities, and any liquidation, dissolution or winding up of the Company, the holders of Series A Preferred Stock are entitled to receive a distribution of any proceeds based on the 70/30 allocation with the holders of Common Stock, (as adjusted for any stock splits, stock dividends, combinations, recapitalizations or the like with respect to the Series A Preferred Stock), plus declared but unpaid dividends on such share.

We may issue from time to time, in one or more offerings pursuant to this registration statement, the following securities:

- shares of Common Stock;
- shares of Preferred Stock;
- debt securities;
- warrants exercisable for debt securities, Common Stock, or preferred stock;
- subscription rights to purchase any of such securities (“Rights”); and
- units of debt securities, Common Stock, Preferred Stock, or warrants, in any combination.

This prospectus contains a summary of the material general terms of the various securities that we may offer. The material general terms of our Common Stock and Preferred Stock are above. The specific terms of the securities will be described in a prospectus supplement, information incorporated by reference or related free writing prospectus, which may be in addition to or different from the general terms summarized in this prospectus. Where applicable, the prospectus supplement, information incorporated by reference or related free writing prospectus will also describe any material United States federal income tax considerations relating to the securities offered and indicate whether the securities offered are or will be listed on any securities exchange. The summaries contained in this prospectus and in any prospectus supplements, information incorporated by reference or related free writing prospectus may not contain all of the information that you would find useful. Accordingly, you should read the actual documents relating to any securities sold pursuant to this prospectus.

The terms of any particular offering, the initial offering price and the net proceeds to us will be contained in the prospectus supplement, information incorporated by reference or free writing prospectus, relating to such offering.

Description of Rights

We may issue rights to purchase our securities. The rights may or may not be transferable by the persons purchasing or receiving the rights. In connection with any rights offering, we may enter into a standby underwriting or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. Each series of rights will be issued under a separate rights agent agreement to be entered into between us and one or more banks, trust companies or other financial institutions, as rights agent that we will name in the applicable prospectus supplement. The rights agent will act solely as our agent in connection with the rights and will not assume any obligation or relationship of agency or trust for or with any holders of rights certificates or beneficial owners of rights.

The prospectus supplement relating to any rights that we offer will include specific terms relating to the offering, including, among other matters:

- the date of determining the security holders entitled to the rights distribution;
- the aggregate number of rights issued and the aggregate amount of securities purchasable upon exercise of the rights;
- the exercise price;
- the conditions to completion of the rights offering;
- the date on which the right to exercise the rights will commence and the date on which the rights will expire; and
- any applicable federal income tax considerations.

Each right would entitle the holder of the rights to purchase for cash the principal amount of securities at the exercise price set forth in the applicable prospectus supplement. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement. After the close of business on the expiration date, all unexercised rights will become void.

If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than our security holders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby arrangements, as described in the applicable prospectus supplement.

Description of Warrants

We may issue warrants to purchase our Common Stock or preferred shares. Warrants may be issued independently or together with any other securities that may be sold by us pursuant to this prospectus or any combination of the foregoing and may be attached to, or separate from, such securities. To the extent warrants that we issue are to be publicly traded, each series of such warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe in particular the terms of any series of warrants that we may offer in more detail in the applicable prospectus supplement and any applicable free writing prospectus. The terms of any warrants offered under a prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of the warrant and/or warrant agreement, if any, which may include a form of warrant certificate, as applicable that describes the terms of the particular series of warrants we may offer before the issuance of the related series of warrants. We may issue the warrants under a warrant agreement that we will enter into with a warrant agent to be selected by us. The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any registered holders of warrants or beneficial owners of warrants. The following summary of material provisions of the warrants and warrant agreements is subject to, and qualified in its entirety by reference to, all the provisions of the form of warrant and/or warrant agreement and warrant certificate applicable to a particular series of warrants. We urge you to read the applicable prospectus supplement and any related free writing prospectus, as well as the complete form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the warrants.

The particular terms of any issue of warrants will be described in the prospectus supplement relating to the issue. Those terms may include:

- the title of the warrants;
- the price or prices at which the warrants will be issued;

- the designation, amount and terms of the securities or other rights for which the warrants are exercisable;
- the designation and terms of the other securities, if any, with which the warrants are to be issued and the number of warrants issued with each other security;
- the aggregate number of warrants;
- any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;
- the price or prices at which the securities or other rights purchasable upon exercise of the warrants may be purchased;
- if applicable, the date on and after which the warrants and the securities or other rights purchasable upon exercise of the warrants will be separately transferable;
- a discussion of any material U.S. federal income tax considerations applicable to the exercise of the warrants;
- the date on which the right to exercise the warrants will commence, and the date on which the right will expire;
- the maximum or minimum number of warrants that may be exercised at any time;
- information with respect to book-entry procedures, if any; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Exercise of Warrants

Each warrant will entitle the holder of warrants to purchase the number of Common Stock or preferred shares of the relevant class or series at the exercise price stated or determinable in the prospectus supplement for the warrants. Warrants may be exercised at any time up to the close of business on the expiration date shown in the applicable prospectus supplement, unless otherwise specified in such prospectus supplement. After the close of business on the expiration date, if applicable, unexercised warrants will become void. Warrants may be exercised in the manner described in the applicable prospectus supplement. When the warrant holder makes the payment and properly completes and signs the warrant certificate at the corporate trust office of the warrant agent, if any, or any other office indicated in the prospectus supplement, we will, as soon as possible, forward the securities or other rights that the warrant holder has purchased. If the warrant holder exercises less than all of the warrants represented by the warrant certificate, we will issue a new warrant certificate for the remaining warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Prior to the exercise of any warrants to purchase Common Stock or preferred shares of the relevant class or series, holders of the warrants will not have any of the rights of holders of Common Stock or preferred shares purchasable upon exercise, including the right to vote or to receive any payments of dividends or payments upon our liquidation, dissolution or winding up on the Common Stock or preferred shares purchasable upon exercise, if any.

Enforceability of Rights by Holders of Warrants

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Outstanding Warrants

As of September 16, 2026, we have common stock purchase warrants to purchase up to 200,000 shares of Common Stock outstanding, with an exercise price of \$0.01 per share.

Description of Units

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement and any related free writing prospectus. The terms of any units offered under a prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from another report we file with the SEC, the form of unit agreement that describes the terms of the series of units we may offer under this prospectus, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplement and any related free writing prospectus, as well as the complete unit agreement and any supplemental agreements that contain the terms of the units.

We may issue units comprised of Common Stock or preferred shares and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. If we offer any units, certain terms of that series of units will be described in the applicable prospectus supplement, including, without limitation, the following, as applicable:

- the title of the series of units;
- identification and description of the separate constituent securities comprising the units;
- the price or prices at which the units will be issued;
- the date, if any, on and after which the constituent securities comprising the units will be separately transferable, if applicable;
- any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities comprising the units;
- a discussion of certain United States federal income tax considerations applicable to the units; and
- any other material terms of the units and their constituent securities.

The provisions described in this section, as well as those described under “Description of Securities” will apply to each unit and to any Common Stock, preferred shares or warrant included in each unit, respectively.

Issuance in Series

We may issue units in such amounts and in numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

We may enter into unit agreements with a unit agent. Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

We, the unit agents and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purpose and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary.

Description of Debt Securities

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will generally apply to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below. As of the date of this prospectus, we have no outstanding registered debt securities.

We may issue notes under senior or subordinated indentures or, separately, without the use of an indenture. If we issue senior or subordinated notes without the use of an indenture, we will issue such senior or subordinated notes directly to the purchasers of such senior or subordinated notes.

If we issue senior notes under a senior indenture, we will enter into such subordinated indenture with the trustee to be named in such senior indenture. If we issue subordinated notes under a subordinated indenture, we will enter into such subordinated indenture with the trustee to be named in such subordinated indenture. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of such notes and indentures, if any, that describes the terms of the particular note we may offer under this prospectus, and any supplement agreements, before the issuance of the related note. We use the term “indentures” to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939. References to the Trust Indenture Act of 1939 include all amendments thereto. We use the term “debenture trustee” to refer to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of material provisions of the senior notes, the subordinated notes and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities, and all supplements thereto. We urge you to read the applicable prospectus supplements related to the debt securities that we sell under this prospectus, as well as the complete indentures that contain the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior and the subordinated indentures are identical.

The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of debt securities and any indentures are summaries of these provisions, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the debt securities and the indentures (including any amendments or supplements we may enter into from time to time which are permitted under the debt securities or any indenture).

General

The terms of each series of debt securities will be established by or pursuant to a resolution of our board of directors and set forth or determined in the manner provided in an officers’ certificate or by a supplemental indenture. Debt securities may be issued in separate series without limitation as to aggregate principal amount. We may specify a maximum aggregate principal amount for the debt securities of any series. In addition, the particular terms of each series of debt securities will be described in a prospectus supplement relating to such series, including any pricing supplement. The prospectus supplement will set forth, among other things:

- the title;
- the principal amount being offered, and, if a series, the total amount authorized and the total amount outstanding;
- any limit on the amount that may be issued;

- whether or not we will issue the series of debt securities in global form and, if so, the terms and who the depositary will be;
- the maturity date;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a U.S. person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate, the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- the terms of the subordination of any series of subordinated debt, if applicable;
- the place where payments will be payable;
- restrictions on transfer, sale, or other assignment, if any;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- the date, if any, after which, the conditions upon which, and the price at which we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions, and any other applicable terms of those redemption provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- whether the indenture will restrict our ability and/or the ability of our subsidiaries to, among other things:
 - incur additional indebtedness;
 - issue additional securities;
 - create liens;
 - pay dividends and make distributions in respect of our capital stock and the capital stock of our subsidiaries;
 - redeem capital stock;
 - place restrictions on our subsidiaries' ability to pay dividends, make distributions or transfer assets;
 - make investments or other restricted payments;
 - sell or otherwise dispose of assets;
 - enter into sale-leaseback transactions;
 - engage in transactions with stockholders and affiliates;
 - issue or sell stock of our subsidiaries;

- effect a consolidation or merger;
- whether the indenture will require us to maintain any interest coverage, fixed charge, cash flow-based, asset-based, or other financial ratios;
- information describing any book-entry features;
- provisions for a sinking fund purchase or other analogous fund, if any;
- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an “original issue discount” as defined in paragraph (a) of Section 1273 of the Internal Revenue Code;
- the procedures for any auction and remarketing, if any;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- if other than dollars, the currency in which the series of debt securities will be denominated; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, including any events of default that are in addition to those described in this prospectus or any covenants provided with respect to the debt securities that are in addition to those described above, and any terms that may be required by us or advisable under applicable laws or regulations or advisable in connection with the marketing of the debt securities.

Conversion or Exchange Rights

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for Common Stock, preferred shares, or other securities of ours or a third party, including the conversion or exchange rate, as applicable, or how it will be calculated, and the applicable conversion or exchange period. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of our securities or the securities of a third party that the holders of the series of debt securities receive upon conversion or exchange would, under the circumstances described in those provisions, be subject to adjustment, or pursuant to which those holders would, under those circumstances, receive other property upon conversion or exchange, for example in the event of our merger or consolidation with another entity.

Consolidation, Merger or Sale

The indentures in the forms initially filed as exhibits to the registration statement of which this prospectus is a part do not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer, or otherwise dispose of all or substantially all of our assets. However, any successor of ours or the acquirer of such assets must assume all of our obligations under the indentures and the debt securities.

If the debt securities are convertible for our other securities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities that the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default Under the Indenture

The following are events of default under the indentures in the forms initially filed as exhibits to the registration statement with respect to any series of debt securities that we may issue:

- if we fail to pay interest when due and payable and our failure continues for 90 days and the time for payment has not been extended or deferred;
- if we fail to pay the principal, sinking fund payment or premium, if any, when due and payable and the time for payment has not been extended or delayed;

- if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the debenture trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the debenture trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the debenture trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

- the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity, to the debenture trustee to institute the proceeding as trustee; and
- the debenture trustee does not institute the proceeding and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters, including:

- to fix any ambiguity, defect or inconsistency in the indenture;
- to comply with the provisions described above under “Consolidation, Merger or Sale”;
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act of 1939;
- to evidence and provide for the acceptance of appointment by a successor trustee;
- to provide for uncertificated debt securities and to make all appropriate changes for such purpose;
- to add to, delete from, or revise the conditions, limitations and restrictions on the authorized amount, terms or purposes of issuance, authorization and delivery of debt securities or any series, as set forth in the indenture;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided under “General” to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default, or to surrender any of our rights or powers under the indenture; or
- to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except that the following obligations, among others survive until the maturity date or the redemption date:

- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;

- maintain paying agencies;
- hold monies for payment in trust;
- appoint any successor trustee; and the following obligations survive the maturity date or the redemption date;
- recover excess money held by the debenture trustee; and
- compensate and indemnify the debenture trustee.

As more fully set forth in the indentures, in order to exercise our rights to be discharged, we must either deliver for cancellation all securities of a series to the debenture trustee or must deposit with the debenture trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company, New York, New York, known as DTC, or another depository named by us and identified in a prospectus supplement with respect to that series.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in a board resolution the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of any series being redeemed in part during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses, and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will name in the applicable board resolution any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

Subordination of Subordinated Debt Securities

The subordinated debt securities will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The indentures in the forms initially filed as exhibits to the registration statement of which this prospectus is a part do not limit the amount of indebtedness that we may incur, including senior indebtedness or subordinated indebtedness, and do not limit us from issuing any other debt, including secured debt or unsecured debt.

Anti-Takeover Provisions

Certain provisions of Delaware law, our Certificate of Incorporation and our Bylaws may have the effect of delaying, deferring or discouraging another person from acquiring control of the Company.

Among other things, the Charter and Bylaws:

- permit the Board to issue up to 10,000,000 shares of preferred stock, with any rights, preferences, and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the authorized number of directors may be changed only by resolution of the Board;

- provide that the Board is classified into three classes of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by the Company's stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of the Company's stockholders may be called only by the Board, the chairperson of the Board, the Company's Chief Executive Officer or upon the written request by a majority of the shareholders entitled to vote; and
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the voting power of the stock of the Company entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of the Company's then-outstanding capital stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions makes it more difficult for the Company's existing stockholders to replace the Board as well as for another party to obtain control of us by replacing the Board. Since the Board has the power to retain and discharge the Company's officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the Company's control.

These provisions are intended to enhance the likelihood of continued stability in the composition of the Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce the Company's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for the Company's shares and may have the effect of delaying changes in the Company's control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of the Company's stock.

Certain Anti-Takeover Provisions of Delaware Law

Special Meetings of Stockholders

The Charter and the Bylaws provide that special meetings of the Company's stockholders may be called only by the Board, the Chairman of the Board, the Chief Executive Officer of the Company, or upon the written request by a majority of the shareholders entitled to vote.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

The Bylaws provide that stockholders seeking to nominate candidates for election to the Board or to bring business before the Company's annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely under the Bylaws, a stockholder's notice needs to be received by the Secretary of the Company at the Company's principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting provided, however, that in the event that no annual meeting was held during the preceding year or the date of the annual meeting is advanced more than 30 days prior to or delayed by more than 60 days after the anniversary of the date of the preceding year's annual meeting, notice by the stockholder to be timely must be so received not earlier than the close of business on the 120th day prior to such annual meeting and no later than the close of business on the later of the 90th day prior to such annual meeting or the tenth day following the day on which public announcement of the date of such meeting is first made by the Company. The Bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude the Company's stockholders from bringing matters before its annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Exclusive Forum Selection

The Charter provides that unless the Company consents in writing to the selection of an alternative forum to the fullest extent permitted by the applicable law, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for the following claims or causes of action under Delaware statutory or common law: (a) any derivative claim or cause of action brought on behalf of the Company; (b) any claim or cause of action for breach of a fiduciary duty owed by any current or former director, officer or other employee of the Company, to the Company or its stockholders; (c) any claim or cause of action against the Company or any current or former director, officer or other employee of the Company, arising out of or pursuant to any provision of the DGCL, the Charter or the Bylaws; (d) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the Charter or the Bylaws; (e) any claim or cause of action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and (f) any claim or cause of action against the Company or any current or former director, officer or other employee of the Company, governed by the internal-affairs doctrine or otherwise related to the Company's internal affairs, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. The Charter also requires that unless the Company consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The above shall not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Although the Company believes these provisions benefit us by providing increased consistency in the application of the DGCL in the types of lawsuits to which it applies, a court may determine that these provisions are unenforceable, and to the extent they are enforceable, the provisions may have the effect of discouraging lawsuits against the Company's directors and officers, although the Company's stockholders will not be deemed to have waived its compliance with federal securities laws and the rules and regulations thereunder.

Section 203 of the Delaware General Corporation Law

We have opted out of the provisions of Section 203 of the DGCL regulating corporate takeovers under the Charter. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of the Company's outstanding voting stock (otherwise known as an "interested stockholder");

- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A “business combination” includes a merger or sale of more than 10% of the Company’s assets. However, the above provisions of Section 203 do not apply if:

- our Board approves the transaction that made the stockholder an “interested stockholder,” prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of the Company’s voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the initial business combination is approved by the Board and authorized at a meeting of the Company’s stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Under certain circumstances, this provision makes it more difficult for a person who would be an “interested stockholder” to effect various business combinations with the Company for a three-year period. This provision may encourage companies interested in acquiring us to negotiate in advance with the Board because the stockholder approval requirement would be avoided if the Board approves either the business combination or the transaction which results in the stockholder becoming an interested stockholder. These provisions also may have the effect of preventing changes in the Board and may make it more difficult to accomplish transactions which stockholders may otherwise deem to be in their best interests.

Limitations on Liability and Indemnification of Officers and Directors

The Charter eliminates the Company’s directors’ liability for monetary damages to the fullest extent permitted by applicable law. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any transaction from which the director derives an improper personal benefit;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for any unlawful payment of dividends or redemption of shares; or
- for any breach of a director’s duty of loyalty to the corporation or its stockholders.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the Company’s directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

The Charter requires the Company to indemnify and advance expenses to the fullest extent permitted by applicable law, to its directors, officers, and agents. The Company maintains a directors' and officers' insurance policy pursuant to which the Company's directors and officers are insured against liability for actions taken in their capacities as directors and officers. Finally, the Charter prohibits any retroactive changes to the rights or protections or increase the liability of any director in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

In addition, the Company has entered into separate indemnification agreements with the Company's directors and officers. These agreements, among other things, require the Company to indemnify its directors and officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as one of the Company's directors or officers or any other company or enterprise to which the person provides services at the Company's request.

We believe these provisions in the Charter are necessary to attract and retain qualified persons as directors and officers.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, the Company's stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

1 State Street 30th Floor
New York, NY 10004-1571
212.845.3299
www.continentalstock.com

PLAN OF DISTRIBUTION

We may offer, from time to time, up to \$75,000,000 of common stock, preferred stock, warrants, subscription rights, debt securities and/or units consisting of some or all of these securities in one or more underwritten public offerings, at-the-market offerings, negotiated transactions, block trades, best efforts or a combination of these methods.

We may sell our securities through underwriters or dealers, “at-the-market” to or through a market maker into an existing trading market or otherwise directly to one or more purchasers or through agents or through a combination of methods of sale. The securities may be distributed at a fixed price or prices, which may be changed, market prices prevailing at the time of sale, prices related to the prevailing market prices, or negotiated prices. The prospectus supplement will include the following information:

- the terms of the offering;
- the names of any underwriters or agents;
- the name or names of any managing underwriter or underwriters;
- the purchase price of the securities;
- any over-allotment options under which underwriters may purchase additional securities from us;
- the net proceeds from the sale of the securities;
- any delayed delivery arrangements;
- any underwriting discounts, commissions and other items constituting underwriters’ compensation;
- any offering price;
- any discounts or concessions allowed or reallocated or paid to dealers;
- any commissions paid to agents; and
- any securities exchange or market on which the securities may be listed.

Sale Through Underwriters or Dealers

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement. If underwriters are used in the sale, the underwriters will acquire the securities for their own account, including through underwriting, purchase, security lending or repurchase agreements with us. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions. Underwriters may sell the securities in order to facilitate transactions in any of our other securities (described in this prospectus or otherwise), including other public or private transactions and short sales. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless otherwise indicated in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change from time to time any offering price and any discounts or concessions allowed or reallocated or paid to dealers.

If dealers are used in the sale of securities offered through this prospectus, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. The prospectus supplement will include the names of the dealers and the terms of the transaction.

We will provide in the applicable prospectus supplement any compensation we will pay to underwriters, dealers, or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers.

Direct Sales and Sales Through Agents

We may sell the securities offered through this prospectus directly. In this case, no underwriters or agents would be involved. Such securities may also be sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the offered securities and will describe any commissions payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

Delayed Delivery Contracts

If the prospectus supplement indicates, we may authorize agents, underwriters, or dealers to solicit offers from certain types of institutions to purchase securities at the offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The applicable prospectus supplement will describe the commission payable for solicitation of those contracts.

Market Making, Stabilization and Other Transactions

Unless the applicable prospectus supplement states otherwise, other than our common stock, all securities we offer under this prospectus will be a new issue and will have no established trading market. We may elect to list offered securities on an exchange or in the over-the-counter market. Any underwriters that we use in the sale of offered securities may make a market in such securities but may discontinue such market making at any time without notice. Therefore, we cannot assure you that the securities will have a liquid trading market.

Any underwriter may also engage in stabilizing transactions, syndicate covering transactions and penalty bids in accordance with Rule 104 under the Securities Exchange Act. Stabilizing transactions involve bids to purchase the underlying security in the open market for the purpose of pegging, fixing or maintaining the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the securities to be higher than it would be in the absence of the transactions. The underwriters may, if they commence these transactions, discontinue them at any time.

General Information

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us against certain liabilities, including liabilities under the Securities Act. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered by this prospectus, and any supplement thereto, will be passed upon for us by Hunter Taubman Fischer & Li LLC, New York, NY. The legality of the securities for any underwriters, dealers or agents will be passed upon by counsel as may be specified in the applicable prospectus supplement.

EXPERTS

The consolidated balance sheets of Niki BioSolutions, Inc. (formerly known as Aptorum Group Limited) as of December 31, 2025 and 2024, 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, 2025, and the related notes, included herein have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a *going concern* as described in Note 2 to the financial statements) of Marcum Asia CPAs LLP, an independent registered public accounting firm given on the authority of such firm as experts in accounting and auditing.

The consolidated balance sheets of Diamir Biosciences Corp. as of May 31, 2026 and 2025, and the related consolidated statements of operations, stockholders' deficit and cash flows for each of the two years in the period ended May 31, 2026, incorporated by reference in this prospectus, have been audited by CBIZ CPAs P.C., independent registered public accounting firm, as set forth in their report appearing elsewhere herein, which contains an explanatory paragraph relating to substantial doubt about the ability of Diamir Biosciences Corp. to continue as a going concern as described in Note 2 to the financial statements, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

Material Changes

None.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly, and special reports, along with other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>; you can also find our filings on our company website: nikibio.com and nikibiosolutions.com. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The information on our website is not intended to form a part of or be incorporated by reference into this prospectus.

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC to register the securities offered hereby under the Securities Act of 1933, as amended. This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You may obtain the registration statement and exhibits to the registration statement from the SEC at the address listed above or from the SEC's internet site.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them under certain conditions, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus and any information that we file subsequent to this prospectus with the SEC will automatically update and supersede this information. The documents we are incorporating by reference are as follows:

- the Company's Current Reports on Form 8-K or 8-K/A filed on [July 20, 2026](#), [August 21, 2026](#), [August 21, 2026](#) and [September 4, 2026](#) (except for the portions of such reports deemed to be furnished and not filed); and

Information in the documents referred to above that are incorporated by reference in this prospectus were filed prior to the 1-for-10 reverse split of our common stock that was effective on July 20, 2026, and do not reflect the effects of such reverse stock split.

All documents filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the initial filing date of this prospectus, through the date declared effective, until the termination of the offering of securities contemplated by this prospectus shall be deemed to be incorporated by reference into this prospectus. These documents that we file later with the SEC and that are incorporated by reference in this prospectus will automatically update information contained in this prospectus or that was previously incorporated by reference into this prospectus. You will be deemed to have notice of all information incorporated by reference in this prospectus as if that information was included in this prospectus.

We will provide to any person, including any beneficial owner, to whom this prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus (excluding exhibits, unless the exhibits are specifically incorporated), at no cost to the requesting party, upon request to us in writing or by telephone using the following information:

Ian Huen
Chief Executive Officer
Niki BioSolutions, Inc.
116 Village Boulevard, Suite 200
Princeton, NJ 08540
Tel: 609-951-2222

Disclosure of Commission Position on Indemnification for Securities Act Liabilities.

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

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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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph — Going Concern

The accompanying 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.

Guangzhou, China
March 27, 2026

APTORUM GROUP LIMITED
CONSOLIDATED BALANCE SHEETS
December 31, 2025 and 2024
(Stated in U.S. Dollars, except for number of shares)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,452,891	\$ 874,238
Other receivables and prepayments	139,633	85,316
Total current assets	3,592,524	959,554
Long-term investments, net	15,098,846	15,098,846
Long-term deposits	—	71,823
Total Assets	\$ 18,691,370	\$ 16,130,223
LIABILITIES AND EQUITY		
LIABILITIES		
Current liabilities:		
Amounts due to related parties	\$ 79,180	\$ 79,644
Accounts payable and accrued expenses	1,071,715	918,611
Operating lease liabilities, current	24,428	102,225
Convertible notes to a related party	3,418,500	3,238,500
Total current liabilities	4,593,823	4,338,980
Operating lease liabilities, non-current	—	14,182
Warrant liability	306,000	—
Total Liabilities	4,899,823	4,353,162
Commitments and contingencies (Note 21)	—	—
TEMPORARY EQUITY		
Contingently redeemable warrants	47,000	—
Total temporary equity	47,000	—
EQUITY		
Class A Ordinary Shares (\$0.00001 par value, 9,999,996,000,000 shares authorized, 6,346,823 shares issued and outstanding as of December 31, 2025; 3,811,823 shares issued and outstanding as of December 31, 2024)	62	37
Class B Ordinary Shares (\$0.00001 par value; 4,000,000 shares authorized, 1,796,934 shares issued and outstanding as of December 31, 2025 and 2024)	18	18
Additional paid-in capital	97,000,188	93,474,825
Accumulated other comprehensive (loss) income	(92,310)	89,162
Accumulated deficit	(73,792,798)	(72,429,528)
Total equity attributable to the shareholders of Aptorum Group Limited	23,115,160	21,134,514
Non-controlling interests	(9,370,613)	(9,357,453)
Total equity	13,744,547	11,777,061
Total Liabilities, Temporary Equity and Equity	\$ 18,691,370	\$ 16,130,223

See accompanying notes to the consolidated financial statements.

APTORUM GROUP LIMITED
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For Years Ended December 31, 2025, 2024 and 2023
(Stated in U.S. Dollars, except for number of shares)

	Year Ended December 31, 2025	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	(352,879)	(2,195,161)	(5,198,329)
General and administrative fees	(573,059)	(669,486)	(1,930,637)
Legal and professional fees	(1,062,346)	(803,285)	(2,538,161)
Other operating income (expenses)	170,756	(272,609)	(1,067,690)
Total operating expenses	<u>(1,817,528)</u>	<u>(3,940,541)</u>	<u>(11,155,629)</u>
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	(95,713)	(146,924)	(121,145)
Gain on disposal of subsidiaries	—	703	—
Issuance cost allocated to warrant liability	(153,189)	—	—
Change in fair value of warrant liability	690,000	—	—
Government subsidies	—	928,461	123,015
Sundry income	—	564	36,784
Total other income (expense), net	<u>441,098</u>	<u>(217,196)</u>	<u>6,383,276</u>
Net loss	(1,376,430)	(4,157,737)	(4,340,975)
Net income (loss) attributable to non-controlling interests	13,160	(110,069)	1,516,328
Net loss attributable to Aptorum Group Limited	<u>\$ (1,363,270)</u>	<u>\$ (4,267,806)</u>	<u>(2,824,647)</u>
Net loss per share attributable to Aptorum Group Limited			
– Basic and diluted ⁽¹⁾	<u>\$ (0.19)</u>	<u>\$ (0.78)</u>	<u>(0.62)</u>
Weighted-average shares outstanding			
– Basic and diluted ⁽¹⁾	<u>7,351,784</u>	<u>5,453,103</u>	<u>4,521,133</u>
Net loss	\$ (1,376,430)	\$ (4,157,737)	(4,340,975)
Other comprehensive (loss) income			
Exchange differences on translation of foreign operations	(181,472)	99,785	(44,430)
Other comprehensive (loss) income	<u>(181,472)</u>	<u>99,785</u>	<u>(44,430)</u>
Comprehensive loss	(1,557,902)	(4,057,952)	(4,385,405)
Comprehensive (loss) income attributable to non-controlling interests	(13,160)	110,069	(1,516,328)
Comprehensive loss attributable to the shareholders of Aptorum Group Limited	<u>(1,544,742)</u>	<u>(4,168,021)</u>	<u>(2,869,077)</u>

(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, 2025, 2024 and 2023
(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 income (loss)	Non- Controlling Interests	Total
	Shares ⁽¹⁾	Amount	Shares ⁽¹⁾	Amount	Amount	Amount	Amount	Amount	Amount
Balance, January 1 2023	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
Issuance of Class A Ordinary Shares upon January 2025 Offering	1,535,000	15	—	—	2,699,185	—	—	—	2,699,200
Net loss	—	—	—	—	—	(1,363,270)	—	(13,160)	(1,376,430)
Exchange difference on translation of foreign operations	—	—	—	—	—	—	(181,472)	—	(181,472)
Issuance of Class A Ordinary Shares upon October 2025 Offering	1,000,000	10	—	—	873,178	—	—	—	873,188
Accretion of redemption value to contingently redeemable warrants	—	—	—	—	(47,000)	—	—	—	(47,000)
Balance, December 31, 2025	6,346,823	62	1,796,934	18	97,000,188	(73,792,798)	(92,310)	(9,370,613)	13,744,547

(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, 2025, 2024 and 2023
(Stated in U.S. Dollars)

	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Cash flows from operating activities			
Net loss	\$ (1,376,430)	\$ (4,157,737)	(4,340,975)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization and depreciation	—	255,046	1,125,254
Issuance cost in relation to warrant	153,189	—	—
Change in fair value of warrant liability	(690,000)	—	—
Share-based compensation	—	—	1,265,189
Loss on investments in marketable securities, net	—	—	9,266
Unrealized loss (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
(Gain) loss on disposal of long-lived assets	—	(58,621)	110,852
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
Interest expense and accretion of convertible debts	180,000	180,000	45,266
Reversal of deferred cash bonus	—	—	(1,646,228)
Changes in operating assets and liabilities			
Accounts receivable	—	41,349	126,717
Inventories	—	—	14,516
Other receivables and prepayments	17,506	291,078	227,457
Long-term deposits	—	—	29,106
Amounts due from related parties	—	961	63,050
Amounts due to related parties	(464)	464	(8,524)
Accounts payable and accrued expenses	(28,368)	(422,705)	398,635
Operating lease liabilities	(91,979)	(120,824)	(389,365)
Net cash used in operating activities	<u>(1,836,546)</u>	<u>(1,189,734)</u>	<u>(7,724,364)</u>
Cash flows from investing activities			
Purchases of property and equipment	—	—	(3,015)
Proceeds from disposal of property and equipment	—	58,621	15,385
Proceeds from sales of investment securities	—	—	93,215
Loan to a related party	—	—	(92,459)
Repayment of loan and interest from a related party	—	—	611,641
Net cash provided by investing activities	<u>—</u>	<u>58,621</u>	<u>624,767</u>

APTORUM GROUP LIMITED
CONSOLIDATED STATEMENTS OF CASH FLOWS — (Continued)
For Years Ended December 31, 2025, 2024 and 2023
(Stated in U.S. Dollars)

	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Cash flows from financing activities			
Loan from related parties	—	—	2,500,000
Proceeds from issuance of Class A Ordinary Shares, and warrant	2,000,000	—	1,575,562
Exercise of share options	—	—	16,506
Payments related to offering costs	(284,001)	—	—
Repayment of bank loan	—	—	(3,000,000)
Proceeds from issuance of convertible notes	—	—	3,000,000
Proceeds from issuance of Class A Ordinary Shares	3,070,000	—	—
Payments related to offering costs	(370,800)	—	—
Net cash provided by financing activities	4,415,199	—	4,092,068
 Net increase (decrease) in cash and cash equivalents and restricted cash	 2,578,653	 (1,131,113)	 (3,007,529)
Cash and cash equivalents – Beginning of year	874,238	2,005,351	5,012,880
Cash and cash equivalents – End of year	<u>\$ 3,452,891</u>	<u>\$ 874,238</u>	<u>2,005,351</u>
 Supplemental disclosures of cash flow information			
Interest paid	\$ —	\$ —	94,108
 Non-cash operating, investing and financing activities			
Reclassification of placement agent warrant redemption amount	\$ 47,000	\$ —	—
Right-of-use assets obtained in exchange for new operating lease liabilities	—	—	338,525
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

See accompanying notes to the consolidated financial statements.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

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.

On July 14, 2025 the Group and DiamiR Biosciences Corp. (“DiamiR”), have entered into a definitive agreement for an all-stock merger transaction, in which DiamiR will retain its name and become a wholly-owned subsidiary of Aptorum Group upon consummation of the merger. The combined company expects to remain listed on the Nasdaq Stock Market following the closing of the merger. Under the terms of the merger agreement and subject to stockholder approval, the Company will re-domicile to the state of Delaware prior to the closing of the merger (“Domestication”), and following the Domestication, acquire all of the outstanding capital stock of DiamiR in exchange for a number of shares of its common stock which will represent approximately 70% of the outstanding common stock of the Group, with the current equity holders of the Group retaining 30% of the common stock immediately following the consummation of the merger. The merger agreement has been approved by the boards of directors of both companies, and is subject to stockholder approval of both companies and other customary closing conditions.

Concurrently with the execution of the Merger Agreement, DiamiR and Aptorum Therapeutics, entered into a management services agreement, pursuant to which, Aptorum Therapeutics shall pay a monthly service fee and reimburse expenses to DiamiR in exchange for the officers and employees of DiamiR providing services to Aptorum Therapeutics to develop a diagnostic test for early detection and monitoring of progression of glioblastoma until the earlier of the closing of the Merger or December 31, 2025, and the respective agreement is extended to March 31, 2026, and then further extended to June 30, 2026. In addition, concurrently with the execution of the Merger Agreement, DiamiR, DiamiR LLC, a wholly owned subsidiary of DiamiR, the Company and Aptorum Therapeutics entered into an intellectual property license agreement (“Licensing Agreement”), pursuant to which DiamiR and DiamiR LLC shall license on a non-exclusive basis their respective intellectual properties to Aptorum Therapeutics in exchange for upfront and periodic payments and royalties until the earlier of the closing of the Merger or December 31, 2025, the respective agreement have extended to March 31, 2026, and then further extended to June 30, 2026. Ian Huen, the Group’s Chairman and CEO, who beneficially owns approximately 87% of the Group’s total voting power, signed a voting and support agreement simultaneously with the execution of the Merger Agreement, pursuant to which he agreed to vote in favor of the transactions contemplated in the Merger Agreement.

Below summarizes the list of the major subsidiaries consolidated as of December 31, 2025:

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

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

2. GOING CONCERN

The Group reported a net loss of \$1,376,430 and net operating cash outflow of \$1,836,546 for the year ended December 31, 2025 and had negative working capital of \$1,001,299 as of December 31, 2025. In addition, the Group had an accumulated deficit of \$73,792,798 as of December 31, 2025. 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 Group's cost structure. In connection with the Group'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 Group'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 Group can make no assurances that required financings will be available for the amounts needed, or on terms commercially acceptable to the Group, 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 Group and would materially adversely affect its ability to continue as a going concern.

The Group's 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 States Securities and Exchange Commission (the "SEC"), and include the accounts of the Group, 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 Group 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 Group has a majority ownership interest when we are not considered the primary beneficiary. The Group has determined that the Group is the primary beneficiary of the VIE (see Note 13, Variable Interest Entity). The Group 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.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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, 2025 and 2024, \$522,191 and \$522,191 allowance for credit losses were made. During December 31, 2025, 2024 and 2023, \$nil, \$nil and \$522,191 of allowance for credit losses were made.

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.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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.

APTORUM GROUP LIMITED
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(Stated in U.S. Dollars)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following tables represent the fair value hierarchy of the Group's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2025 and there is no such financial liabilities measured at fair value on a recurring basis as of December 31, 2024.

	As of December 31, 2025			
	Fair Value Measurement at the Reporting Date using			
	Quoted price in active markets for identical assets Level 1	Significant other observable inputs Level 2	Significant unobservable inputs Level 3	Total
Financial liabilities:				
Warrant liabilities	—	—	306,000	306,000
Total	\$ —	\$ —	\$ 306,000	\$ 306,000

The Group has determined that the carrying value of the Group's cash and cash equivalents, other receivables and prepayments, amounts due to related parties, accounts payable and accrued expenses, convertible notes to a related party 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.

APTORUM GROUP LIMITED
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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant’s specific terms and applicable authoritative guidance in Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 480, Distinguishing Liabilities from Equity (“ASC 480”) and ASC 815, Derivatives and Hedging (“ASC 815”). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Group’s own ordinary shares and whether the warrant holders could potentially require “net cash settlement” in a circumstance outside of the Group’s control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the consolidated statements of operations.

For equity-classified warrants that contain redemption features not solely within the control of the Company, the Company evaluates whether temporary equity classification is required pursuant to ASC 480-10-S99-3A. When temporary equity classification is required, the initial amount presented in temporary equity is based on the redemption provisions of the instrument. If the redemption event is contingent and not probable of occurring, no subsequent adjustment to the temporary equity amount is required pursuant to S99-3A Paragraph 15.

Issuance costs

Specific incremental costs directly attributable to an offering of securities are allocated among the freestanding financial instruments issued in the transaction. The Company allocates issuance costs in proportion to the allocation of proceeds between the freestanding financial instruments. Issuance costs allocated to liability-classified instruments that are subsequently measured at fair value through earnings are recognized in earnings in the period incurred. Issuance costs allocated to equity-classified instruments are charged to additional paid-in capital.

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 \$nil, \$0.9 million and \$0.1 for the years ended December 31, 2025, 2024 and 2023, respectively.

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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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. Warrants issued to placement agents or other non-employees in exchange for services rendered in connection with equity offerings are accounted for under ASC 718 and classified as equity when the criteria for equity classification are met. Such warrants are measured at their grant date fair value using the Black-Scholes option pricing model and recognized as issuance costs of the related offering.

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. Penalties and interest incurred related to underpayment of income tax are classified as income tax expense in the period incurred. 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 and the United States, 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, 2025, 2024 and 2023, and did not have any significant unrecognized uncertain tax positions as of December 31, 2025 and 2024. The Group does not believe that its assessment regarding unrecognized tax benefits will materially change over the next twelve months.

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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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 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 adopted ASU 2023-09 from January 1, 2025 on a retrospective basis. The adoption of ASU2023-09 did not have material impact on the Company's consolidated balance sheets, statements of operations and comprehensive loss, changes in equity and cash flows, but resulted in expanded income tax disclosures in Note 11 to the consolidated financial statements.

APTORUM GROUP LIMITED
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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Recently issued accounting standards which have not yet been adopted

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. LONG-TERM INVESTMENT

As of December 31, 2025 and 2024, the Group’s long-term investment consists of non-marketable investments with carrying value of \$15,098,846 and equity method investment at fair value option with carrying value of \$nil.

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 table summarizes the total carrying value of the non-marketable investments held as of December 31, 2025 and 2024 including cumulative unrealized upward adjustments and impairment made to the initial cost basis of the investments:

	December 31, 2025				December 31, 2024			
	Cost basis	Upward adjustments	Impairment	Carrying value	Cost basis	Upward adjustments	Impairment	Carrying value
Investment A ⁽¹⁾	\$ 2,558,886	\$ 12,539,960	\$ —	\$ 15,098,846	\$ 2,558,886	\$ 12,539,960	\$ —	\$ 15,098,846
Investment B ⁽²⁾	1,000,000	—	(1,000,000)	—	1,000,000	—	(1,000,000)	—
Investment C	520,821	—	(520,821)	—	520,821	—	(520,821)	—
	<u>\$ 4,079,707</u>	<u>\$ 12,539,960</u>	<u>\$ (1,520,821)</u>	<u>\$ 15,098,846</u>	<u>\$ 4,079,707</u>	<u>\$ 12,539,960</u>	<u>\$ (1,520,821)</u>	<u>\$ 15,098,846</u>

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, 2025, 2024 and 2023 based on the observable price in an orderly transaction for the same or similar security of the same issuers:

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Upward adjustments ⁽¹⁾	\$ —	\$ —	\$ 6,431,088
Impairment ⁽²⁾	—	(1,000,000)	—
Total unrealized (loss) gain from fair value change of non-marketable investments, net	<u>\$ —</u>	<u>\$ (1,000,000)</u>	<u>\$ 6,431,088</u>

(1) The Group holds 622,600 Series B preferred stock of Alzheon, Inc. (“Alzheon”) with initial cost of \$2.6 million with unit price of \$4.11, which represents 240,773 common stock converted as a conversion rate of \$10.63. Pursuant to ASC 321-10-35-2, as the investment in Alzheon lacks readily determinable fair values, the Group elects to account for this investment using the measurement alternative. The Group reviews Alzheon’s available financial information and adjusts the carrying value of its investment based on preferred stock issuances reflected therein, which were deemed as observable price changes in orderly transactions for the identical or similar investment of the same issuer.

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4. LONG-TERM INVESTMENT (cont.)

During the year ended December 31, 2022, Alzheon issued its Series D preferred stock at \$36.00 per share for aggregate gross proceeds of \$50 million. During the year ended December 31, 2023, Alzheon issued its Series E convertible preferred stock at a per share price of \$62.71 for gross proceeds of \$45 million. During the year ended December 31, 2024, Alzheon issued its Series E convertible preferred stock at a per share price of \$62.71 for gross proceeds of \$78 million. During the year ended December 31, 2025, Alzheon issued its Series E convertible preferred stock at a per share price of \$62.71 for gross proceeds of \$5 million. Aside from the conversion price of the conversion rights being different, the other key terms, including liquidation right, conversion right, voting power, dividend right and redemption right are aligned for Series B, Series D and Series E convertible preferred stocks. The Group determines the Series D and Series E convertible preferred stocks financings are orderly transactions between market participants for the identical or a similar investment of the same issuer and recorded as an upward in the carrying value of the security measured in accordance with paragraph 321-10-35-2 to reflect the current fair value of the security as of the date that the observable transaction for the similar security took place.

The Group made an upward adjustment of \$6,108,872, from \$2,558,886 to \$8,667,758, based on Series D convertible preferred stock financing for the year ended December 31, 2022, and made an upward adjustment of \$6,431,088, from \$8,667,758 to \$15,098,846, based on Series E convertible preferred stock financing for the year ended December 31, 2023. No such upward adjustments were made during the years ended December 31, 2025 and 2024.

The Group conducts a quarterly assessment to determine whether impairment exists in Alzheon's equity securities, considering, among other factors, the nature of the securities, financial condition of Alzheon and expected future cash flows. No impairment indicator was identified, and no impairment was made during the years ended December 31, 2025 and 2024. The carrying value of the investment with Alzheon was \$15,098,846 as of December 31, 2025 and 2024.

As of December 31, 2025 and 2024, this investment was pledged for a convertible note issued to a related party (Note 15).

- (2) The Group holds 3,333,333 Series B preferred stock of Investee B with initial cost of \$1.0 million at a purchase price of \$0.30 per unit. There was no observable orderly transactions of identical or similar securities from the same issuer. The Group monitored the financial statements of the Investee B. The Group recorded \$1 million impairment for this investment in the year ended December 31, 2024 since the Group considered the investees' ability to continue as a going concern and the investment is not recoverable. The carrying value of this investment was \$nil as of December 31, 2025 and 2024, respectively.

The Group did not sell or transfer any non-marketable investments or record 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, 2025, 2024 and 2023.

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. The initial carrying value of the investment was \$77,200. 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, \$nil and \$77,200 has been recognized as of December 31, 2025, 2024 and 2023.

The Company's involvement with Libra includes equity ownership as mentioned in above and also amounts due from Libra as disclosed in note 12. The primary risks associated with this involvement include potential financial losses due to Libra's operational performance or inability to generate sufficient cash flows. The Company's maximum exposure to loss resulting from its involvement with Libra is nil for the year ended December 31, 2025 and December 31, 2024 which was the amount due from Libra.

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5. 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, 2025 and 2024.

For the year ended December 31, 2023, all revenue came from provision of healthcare services in Hong Kong.

6. OTHER RECEIVABLES AND PREPAYMENTS

Other receivables and prepayments as of December 31, 2025 and 2024 consisted of:

	December 31, 2025	December 31, 2024
Prepaid insurance	17,490	17,794
Prepaid service fee	44,810	50,538
Rental deposits	71,823	4,206
Other receivables	—	4,545
Other deposits	5,510	8,233
	<u>\$ 139,633</u>	<u>\$ 85,316</u>

For the years ended December 31, 2025, 2024 and 2023, the Group considered certain other receivables and prepayments were not recoverable and recorded write-off of other receivables and prepayments of \$nil, \$45,677 and \$62,369, respectively.

7. PROPERTY AND EQUIPMENT, NET

Property and equipment as of December 31, 2025 and 2024 consisted of:

	December 31, 2025	December 31, 2024
Computer equipment	\$ 69,291	\$ 69,291
Furniture, fixture, and office and medical equipment	32,435	32,435
Leasehold improvements	108,187	108,187
Laboratory equipment	4,335,722	4,335,722
Motor vehicle	239,093	239,093
	<u>4,784,728</u>	<u>4,784,728</u>
Less: accumulated depreciation	4,784,728	4,784,728
Property and equipment, net	<u>\$ —</u>	<u>\$ —</u>

Depreciation expenses for property, plant and equipment amounted to \$nil, \$235,827 and \$1,041,234 for the years ended December 31, 2025, 2024 and 2023 respectively.

For the year ended December 31, 2025, no impairment loss was recorded.

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, 2025 and 2024, the Group recorded \$nil and \$58,621 gain on disposal of medical equipment in other operation expenses, respectively. 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.

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8. INTANGIBLE ASSETS, NET

	December 31, 2025	December 31, 2024
Gross carrying amount		
Prepaid patented licenses	\$ 200,000	\$ 200,000
Computer software	223,858	223,858
	<u>423,858</u>	<u>423,858</u>
Less: accumulated amortization		
Prepaid patented licenses	200,000	200,000
Computer software	223,858	223,858
	<u>423,858</u>	<u>423,858</u>
Intangible assets, net		
Prepaid patented licenses	—	—
Computer software	—	—
Intangible assets, net	<u>\$ —</u>	<u>\$ —</u>

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 \$nil and \$19,219 for the year ended December 31, 2025 and 2024 respectively.

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. For the year ended December 31, 2025, the Group terminated 5 of the licenses.

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. There is no such impairment loss during the year ended December 31, 2025.

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, 2025.

9. LONG-TERM DEPOSITS

Long-term deposits as of December 31, 2025 and 2024 consisted of:

	December 31, 2025	December 31, 2024
Rental deposits	\$ —	\$ 71,823
	<u>\$ —</u>	<u>\$ 71,823</u>

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of December 31, 2025 and 2024 consisted of:

	December 31, 2025	December 31, 2024
Research and development expenses payable	\$ 830,189	\$ 778,205
Professional fees payable	185,247	127,031
Others	56,279	13,375
	<u>\$ 1,071,715</u>	<u>\$ 918,611</u>

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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 from Hong Kong during the years ended December 31, 2025, 2024 and 2023. Therefore, no Hong Kong profit tax has been provided for in the periods presented. Our returns for 2019 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, 2025, 2024 and 2023. Therefore, no United Kingdom profit tax has been provided for in the periods presented. Our returns for 2021 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, 2025, 2024 and 2023. Therefore, no Singapore profit tax has been provided for in the periods presented. Our returns for 2021 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, 2025, 2024 and 2023. Therefore, no United States profit tax has been provided for in the periods presented. Our returns for 2022 and subsequent tax years remain subject to examination by Internal Revenue Service.

Income/(loss) before income tax expense is attributable to the following geographic locations:

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Hong Kong	\$ (1,409,614)	\$ (3,944,692)	\$ (1,297,897)
Singapore	111,972	(252,611)	(2,956,296)
Other jurisdictions	(78,788)	39,566	(86,782)
Loss before income tax expense	<u>\$ (1,376,430)</u>	<u>(4,157,737)</u>	<u>(4,340,975)</u>

For the year ended December 31, 2025, 2024 and 2023, there was no current income tax expense and deferred income tax expense.

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11. INCOME TAXES (cont.)

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, 2025		Year ended December 31, 2024		Year ended December 31, 2023	
Net loss before tax	\$ (1,376,430)	100%	\$ (4,157,737)	100%	\$ (4,340,975)	100%
Hongkong statutory income tax rate	16.5%		16.5%		16.5%	
Provision for income tax benefit at Hong Kong statutory income tax rate (16.5%)	(227,110)	16.5%	(686,027)	16.5%	(716,261)	16.5%
Domestic tax effects						
Non-taxable interest income	(13,907)	1.0%	(5,477)	0.1%	(1,071,774)	24.7%
Non-deductible expenses	—	0.0%	195	0.0%	98,704	(2.3)%
Change in valuation allowance	223,918	(16.3)%	702,123	(16.9)%	1,705,603	(39.3)%
Foreign tax effects						
Cayman						
– Statutory tax rate difference between Cayman and Hong Kong	16,128	(1.2)%	(9,191)	0.2%	(5,078)	0.1%
Other foreign jurisdictions	917	0.0%	(1,623)	0.1%	(11,185)	0.3%
Effective income tax expense	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>

Income taxes paid by jurisdiction is as follows:

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Hong Kong	\$ —	\$ —	—
Singapore	—	—	—
Other jurisdictions	—	—	—
Total income taxes paid	<u>\$ —</u>	<u>—</u>	<u>—</u>

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, 2025	December 31, 2024
Deferred tax asset:		
Net operating losses carryforwards	\$ 15,365,786	\$ 15,107,318
Depreciation and amortization	86,843	128,896
Impairment loss on assets	537,830	537,830
Total Deferred tax asset	15,990,459	15,774,044
Valuation allowance	(15,990,459)	(15,774,044)
Deferred tax asset, net of valuation allowance	<u>\$ —</u>	<u>\$ —</u>

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11. INCOME TAXES (cont.)

As of December 31, 2025 and 2024, the Group had net operating losses carryforwards of \$93,107,417 and \$91,436,307, 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, 2025, there was no net operating losses carryforwards expired, while net operating losses carryforwards of \$39,489 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 net operating losses carryforwards, 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:

	December 31, 2025	December 31, 2024	December 31, 2023
Balance as of January 1	\$ 15,774,044	\$ 17,407,156	15,705,088
Additions	223,918	702,123	1,705,603
Disposal	(7,503)	(2,335,235)	(3,535)
Balance as of December 31	<u>\$ 15,990,459</u>	<u>\$ 15,774,044</u>	<u>17,407,156</u>

Uncertain tax position

The Group evaluates each uncertain tax position (including the potential application of interest and penalties) based on the technical merits, and measure the unrecognized benefits associated with the tax positions. As of December 31, 2025 and 2024, the Group did not have any unrecognized uncertain tax positions. For the years ended December 31, 2025, 2024 and 2023, the Company did not incur any interest and penalties related to potential underpaid income tax expenses.

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) 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)

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12. RELATED PARTY BALANCES AND TRANSACTIONS (cont.)

Amounts due from related parties, net

Amounts due from related parties consisted of the following as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Current		
Libra Sciences Limited (Note b)	522,192	522,192
Allowance for credit loss	(522,192)	(522,192)
Total	\$ —	\$ —

Amounts due to related parties

Amounts due to related parties consisted of the following as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Current		
Aeneas Group Limited (Note a)	\$ 79,180	\$ 79,180
Ian Huen	—	464
	\$ 79,180	\$ 79,644
Convertible notes to a related party		
Jurchen Investment Corporation (Note 15)	3,418,500	3,238,500
Total	\$ 3,418,500	\$ 3,238,500

Related party transactions

Related party transactions consisted of the following for the years ended December 31, 2025, 2024 and 2023:

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Loan from related parties (Note a)			
– Aeneas Group Limited	\$ —	\$ —	\$ 2,500,000
Issuance of Convertible Note to related parties (Note 15)			
– Jurchen Investment Corporation	\$ —	\$ —	\$ 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
– Jurchen Investment Corporation	\$ 180,000	\$ 180,000	\$ 58,500
– Aenco Technologies Ltd	\$ —	\$ —	\$ (13,234)
Loan to related parties (Note b)			
– Libra Sciences Limited	\$ —	\$ —	\$ 92,459
Loan repayment and interest received from a related party (Note b)			
– Talem Medical Group Limited	\$ —	\$ —	\$ 611,641

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12. RELATED PARTY BALANCES AND TRANSACTIONS (cont.)

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Interest income (Note b)			
– Talem Medical Group Limited	\$ —	\$ —	\$ 4,637
– Libra Sciences Limited	\$ —	\$ —	\$ 8,963
Consultant, secondment, management and administrative services fees (Note c)			
– CGY Investments Limited	\$ —	\$ —	\$ 153,640
– ACC Medical Limited	\$ —	\$ —	\$ 138,768
Administrative management services (Note d)			
– Libra Sciences Limited	\$ —	\$ —	\$ 9,615
Healthcare services income			
– Aeneas Management Limited	\$ —	\$ —	\$ 961

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 four years to August 12, 2026. 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 AUD 4,700,000 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, 2025, 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 \$nil, \$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 agreed to suspend 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.

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12. RELATED PARTY BALANCES AND TRANSACTIONS (cont.)

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.

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.

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13. VARIABLE INTEREST ENTITY (cont.)

As at the year ended December 31, 2025 and 2024, there is no consolidated VIE and Libra is the only unconsolidated VIE. The unconsolidated asset and liability of VIE Libra is \$61,873 and \$691,253 respectively for both year ended December 31, 2025 and 2024.

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. Since Libra is in net liability position and the investment amount by the group in Libra as well as the amount due from Libra was fully impaired in 2024, and there is no obligation for further financing commitment or obligation for absorbing loss, the maximum exposure to loss from its involvement with Libra is zero.

14. LEASE

As of December 31, 2025, the Group has a long-term operating lease for laboratories with remaining term expiring in 2026 and a remaining lease term of 0.2 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, 2025	For the year ended December 31, 2024	For the year ended December 31, 2023
Lease cost			
Operating lease cost	—	50,520	252,345
Short-term lease cost	—	3,374	65,221
Total lease cost	<u>\$ —</u>	<u>\$ 53,894</u>	<u>317,566</u>
Other information			
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows from operating leases	\$ 98,448	\$ 120,824	389,365
Weighted-average remaining lease term – operating leases	0.2 years	1.2 years	1.9 years
Weighted-average discount rate – finance leases	—%	—%	—%
Weighted-average discount rate – operating leases	8.0%	8.0%	8.0%

For the years ended December 31, 2025, the Group did not recognize any impairment losses and loss on disposal of right-of-use assets.

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.

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14. LEASE (cont.)

The maturity analysis of operating leases liabilities as of December 31, 2025 is as follows:

	December 31, 2025
Remaining periods ending December 31, 2026	24,573
Total future undiscounted cash flow	24,573
Less: Discount on operating lease liabilities	(145)
Present value of operating lease liabilities	24,428

15. CONVERTIBLE NOTE

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 4). 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 January 23, 2023, the Company effectuated 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.

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.

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16. ORDINARY SHARES (cont.)

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).

For the year ended December 31, 2024 and 2023, the Group issued 427,060 and 791 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.

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 “January 2025 Offering”) and the net proceeds after deducting the related expense is \$2,699,200. The Securities Purchase Agreement was fully executed on January 3, 2025.

On October 14, 2025, the Company closed an offering of 1,000,000 Class A ordinary shares at a purchase price of \$2.00 per unit, with each unit consisting of one Class A ordinary share and two restricted warrants (the “Investor Warrants”, see Note 20) to purchase one Class A ordinary share each, for aggregate gross proceeds of \$2,000,000 (the “October 2025 Offering”). Cash issuance costs are \$284,001 and the net proceeds from the October 2025 Offering were approximately \$1,716,000.

Of the \$2,000,000 gross proceeds, \$996,000 was allocated to the liability-classified Investor Warrants at their fair value (see Note 20), with the residual \$1,004,000 allocated to the equity-classified Class A ordinary shares.

In connection with the October 2025 Offering, the Company issued warrants to purchase 60,180 Class A ordinary shares to the placement agent’s designees (the “Placement Agent Warrants”) at an exercise price of \$2.50 per share. The Placement Agent Warrants had a grant-date fair value of \$23,606 (see Note 17) which was treated as an issuance cost of the offering.

Cash issuance costs of \$284,001 and the Placement Agent Warrant fair value of \$23,606 were allocated between the liability and equity instruments in proportion to the allocation of proceeds (\$141,433 and \$11,756, respectively, to the warrant liability, expensed as incurred; and \$142,568 and \$11,850, respectively, to equity, charged to additional paid-in capital).

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.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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17. SHARE BASED COMPENSATION (cont.)

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, 2025, 2024 and 2023 changes during the period are presented below:

	Number of share options ⁽¹⁾	Weighted average exercise price \$	Remaining contractual term in years	Aggregate Intrinsic value
Outstanding, January 1, 2025	—	—	—	—
Outstanding, December 31, 2025	—	—	—	—
Exercisable, December 31, 2025	—	—	—	—
Vested, December 31, 2025	—	—	—	—
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	—	—	—	—
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	—

(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 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.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

17. SHARE BASED COMPENSATION (cont.)

Placement agent warrants

In connection with the October 2025 Offering (see Note 16), the Company issued warrants to purchase 60,180 Class A ordinary shares to the placement agent's designees at an exercise price of \$2.50 per share. The Placement Agent Warrants were immediately exercisable upon issuance on October 10, 2025 and expire on the earlier of 24 months from the effective date of a registration statement or October 10, 2030. The Placement Agent Warrants are accounted for under ASC 718 as share-based compensation issued in exchange for services. The grant date fair value of the Placement Agent Warrants was \$23,606 which was treated as an issuance cost of the October 2025 Offering (see Note 16). The Placement Agent Warrants were classified as temporary equity under ASC 480-10-S99-3A due to certain contingent redemption provisions in the warrant. The contractual redemption amount of the Placement Agent Warrants on the issuance date was \$47,000, which was reclassified from additional paid-in capital to temporary equity. Since the contingent event is not probable to occur, no subsequent remeasurement of the temporary equity amount is required. See Note 20 for additional information regarding warrants.

18. NON-CONTROLLING INTEREST

On February 1, 2023, Aptorum Medical Limited 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 was reclassified from additional paid-in capital to non-controlling interests within the Group's consolidated financial statements for the years ended December 31, 2023.

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, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Numerator:			
Net loss attributable to Aptorum Group Limited	\$ (1,363,270)	\$ (4,267,806)	(2,824,647)
Denominator:			
Basic and diluted weighted average shares outstanding	7,351,784	5,453,103	4,521,133
Net loss per share attributable to Aptorum Group Limited ⁽¹⁾			
Basic and diluted loss per share	\$ (0.19)	\$ (0.78)	(0.62)

Basic loss per share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted 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. For the year ended December 31, 2025, 2024 and 2023, 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 3,452,457, 1,392,277 and 1,293,723, respectively.

20. WARRANTS

In connection with the October 2025 Offering (see Note 16), the Company issued Investor Warrants to purchase 2,000,000 Class A ordinary shares and Placement Agent Warrants to purchase 60,180 Class A ordinary shares.

The Investor Warrants are exercisable immediately at an exercise price of \$2.00 per share and expire twenty-four months from the effective date of a registration statement registering for resale the ordinary shares underlying the Investor Warrants. The Investor Warrants were classified as liabilities under ASC 815 due to certain settlement provisions that preclude equity classification.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

20. WARRANTS (cont.)

The fair value of the Investor Warrants was determined using a binomial option pricing model with the following inputs:

	As of October 14, 2025	As of December 31, 2025
Stock price	\$ 1.59	\$ 1.06
Exercise price	\$ 2.00	\$ 2.00
Expected term	2.5 years	1.93 years
Risk-free rate	3.49%	3.48%
Expected volatility	58.80%	58.10%
Dividend rate	0.00%	0.00%
Dilution factor	1	1
Fair value per share	\$ 0.498	\$ 0.153

Expected volatility was based on the historical volatility of comparable publicly traded companies. The Company recognized a gain of \$690,000 on the change in fair value of the Investor Warrant liability for the year ended December 31, 2025, included in “Change in fair value of warrant liability” in the consolidated statements of operations.

The Placement Agent Warrants are exercisable immediately upon issuance and expire on the earlier of (i) 24 months from the effective date of a registration statement or (ii) October 10, 2030.

The grant-date fair value of the Placement Agent Warrants was \$23,606, determined using the Black-Scholes option pricing model with the following inputs: stock price of \$1.59, exercise price of \$2.50, expected term of 2.5 years, risk-free rate of 3.48%, and expected volatility of 58.8% based on comparable public companies. The fair value of the Placement Agent Warrants was treated as an issuance cost of the October 2025 Offering (see Note 16). See Note 20 for additional information regarding warrants.

The Placement Agent Warrants were classified as temporary equity under ASC 480-10-S99-3A due to certain contingent redemption provisions in the warrant. The contractual redemption amount of the Placement Agent Warrants on the issuance date was \$47,000, computed using the following contractually specified inputs: stock price of \$1.59, exercise price of \$2.50, expected volatility of 100%, risk-free rate of 3.48%, and remaining term of 2.5 years. This amount was reclassified from additional paid-in capital to temporary equity on the issuance date. Since the contingent event is not probable to occur, no subsequent remeasurement of the temporary equity amount is required.

As of December 31, 2025, the Company had 2,060,180 warrants outstanding to purchase Class A ordinary shares with a weighted-average exercise price of \$2.01 and a weighted-average remaining contractual term of approximately 1.9 years.

21. COMMITMENTS AND CONTINGENCIES

Contingent Payment Obligations

As of December 31, 2025, 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.

APTORUM GROUP LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Stated in U.S. Dollars)

21. COMMITMENTS AND CONTINGENCIES (cont.)

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, 2025 are below:

	<u>Amount</u>
Drug molecules: up to the conditions and milestones of	
From entering phase 1 to before first commercial sale	920,000
First commercial sale	800,000
Net sales amount more than certain threshold in a year	<u>7,000,000</u>
Subtotal	<u>\$ 8,720,000</u>

For the years ended December 31, 2025, 2024 and 2023, the Group incurred \$nil, \$61,123 and \$50,000 milestone payments under license agreements, respectively. For the years ended December 31, 2025, 2024 and 2023, the Group did not incur any royalties or research and development funding, respectively.

Legal proceedings

The Group is party to a lawsuit initially filed on notice on September 3, 2024, by Karen Cheung (“Plaintiff”) in the Supreme Court of the State of New York, County of New York (“State Court Action”) (Index No. 654541/2024), which sought relief arising from (i) violations of the federal Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 § U.S.C. 1961(c), (ii) conspiracy to violate RICO, 18 U.S.C. § 1961(d), (iii) fraud, (iii) breach of fiduciary duty, (iv) negligent misrepresentation, (v) unjust enrichment, (vi) civil conspiracy and (vii) violations of the federal Securities Act of 1933, 15 § U.S.C. 77a et. seq. On December 27, 2024, the Group filed a Notice of Removal in the U.S. District Court for the Southern District of New York (Case No.1:24-cv-09969-VSB-OTW) removing the State Court Action to federal court. On December 30, 2024, the Group filed a demand for service of the complaint on the Group. Plaintiff filed and served her Complaint on the Group on February 24, 2025, alleging claims for (i) violations of RICO 18 U.S.C. § 1962(c), (ii) conspiracy to violate RICO 18 U.S.C. § 1962(d), (iii) fraud; (iv) aiding and abetting breach of fiduciary duty, (v) unjust enrichment, and (vi) civil conspiracy. Following a motion, Plaintiff was granted leave to amend her Complaint and filed a First Amended Complaint on September 2, 2025. The parties entered into a briefing schedule on the Group’s anticipated motion to dismiss (“Motion to Dismiss”), and the Group filed its opening brief on the Motion to Dismiss on July 18, 2025. Plaintiff filed her opposition to the Motion to Dismiss on September 5, 2025, and the Company’s reply in support of the Motion to Dismiss is due on October 6, 2025. The Group continues to believe that Plaintiff’s claims have no merit. As such, the Group will continue to vigorously defend against Plaintiff’s claims. At this time, it is too early to estimate the costs and expenses of defending the lawsuit.

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.

22. SUBSEQUENT EVENTS

The Group evaluates all events and transactions that occur after December 31, 2025, there is no subsequent event occurred that would require recognition or disclosure in the Group’s consolidated financial statements.

Niki BioSolutions, Inc.

\$75,000,000
Common Stock
Preferred Stock
Debt Securities
Warrants
Rights
Units

September 18, 2026

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses payable by the registrant in connection with this offering, other than underwriting commissions and discounts, all of which are estimated except for the SEC registration fee.

Securities and Exchange Commission registration fee	\$ 10,357.50
Accounting fees and expenses	\$ 15,450
Legal fees and expenses	\$ 2,829
Miscellaneous expenses	\$ *
Total	\$ 28,636.50

* Estimated expenses are not presently known because they depend upon, among other things, the number of offerings that will be made pursuant to this registration statement, the amount and type of securities being offered and the timing of such offerings; we cannot compute the total until the exact expenses are known.

Item 15. Indemnification of Directors and Officers.

The Registrant's certificate of incorporation (the "Charter") provides that all of the Registrant's directors, officers, employees and agents shall be entitled to be indemnified by the Registrant to the fullest extent permitted by Section 145 of the Delaware General Corporation Law ("DGCL"). Section 145 of the DGCL concerning indemnification of officers, directors, employees, and agents is set forth below.

Section 145. Indemnification of officers, directors, employees, and agents; insurance.

- (a) A corporation shall have power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.
- (b) A corporation shall have power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

- (c) To the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of this section, or in defense of any claim, issue, or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.
- (d) Any indemnification under subsections (a) and (b) of this section (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee, or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in subsections (a) and (b) of this section. Such determination shall be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders.
- (e) Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in this section. Such expenses (including attorneys' fees) incurred by former officers and directors, or other employees and agents may be so paid upon such terms and conditions, if any, as the corporation deems appropriate.
- (f) The indemnification and advancement of expenses provided by, or granted pursuant to, the other subsections of this section shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to such provision after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.
- (g) A corporation shall have power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under this section.
- (h) For purposes of this section, references to "the corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under this section with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued.

- (i) For purposes of this section, references to “other enterprises” shall include employee benefit plans; references to “fines” shall include any excise taxes assessed on a person with respect to any employee benefit plan; and references to “serving at the request of the corporation” shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the corporation” as referred to in this section.
- (j) The indemnification and advancement of expenses provided by, or granted pursuant to, this section shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such a person.
- (k) The Court of Chancery is hereby vested with exclusive jurisdiction to hear and determine all actions for advancement of expenses or indemnification brought under this section or under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise. The Court of Chancery may summarily determine a corporation’s obligation to advance expenses (including attorneys’ fees).

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

In accordance with Section 102(b)(7) of the DGCL, the Charter provides that no director shall be personally liable to the Registrant or any of its stockholders for monetary damages resulting from breaches of their fiduciary duty as directors, except to the extent such limitation on or exemption from liability is not permitted under the DGCL. The effect of this provision of the Charter is to eliminate the Registrant’s rights and those of the Registrant’s stockholders (through stockholders’ derivative suits on the Registrant’s behalf) to recover monetary damages against a director for breach of the fiduciary duty of care as a director, including breaches resulting from negligent or grossly negligent behavior, except, as restricted by Section 102(b)(7) of the DGCL. However, this provision does not limit or eliminate the Registrant’s rights or the rights of any stockholder to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director’s duty of care.

If the DGCL is amended to authorize corporate action further eliminating or limiting the liability of directors, then, in accordance with the Charter, the liability of the Registrant’s directors to the Registrant or its stockholders will be eliminated or limited to the fullest extent authorized by the DGCL, as so amended. Any repeal or amendment of provisions of the Charter limiting or eliminating the liability of directors, whether by the Registrant’s stockholders or by changes in law, or the adoption of any other provisions inconsistent therewith, will (unless otherwise required by law) be prospective only, except to the extent such amendment or change in law permits the Registrant to further limit or eliminate the liability of directors on a retroactive basis.

The Charter also provides that the Registrant will, to the fullest extent authorized or permitted by applicable law, indemnify its current and former officers and directors, as well as those persons who, while directors or officers of the Registrant, are or were serving as directors, officers, employees or agents of another entity, trust or other enterprise, including service with respect to an employee benefit plan, in connection with any threatened, pending or completed proceeding, whether civil, criminal, administrative or investigative, against all expense, liability and loss (including, without limitation, attorney’s fees, judgments, fines, ERISA excise taxes and penalties and amounts paid in settlement) reasonably incurred or suffered by any such person in connection with any such proceeding.

Notwithstanding the foregoing, a person eligible for indemnification pursuant to the Charter will be indemnified by the Registrant in connection with a proceeding initiated by such person only if such proceeding was authorized by the Registrant's board of directors, except for proceedings to enforce rights to indemnification.

The right to indemnification which will be conferred by the Charter is a contract right that includes the right to be paid by the Registrant the expenses incurred in defending or otherwise participating in any proceeding referenced above in advance of its final disposition, provided, however, that if the DGCL requires, an advancement of expenses incurred by an officer or director of the Registrant (solely in the capacity as an officer or director of the Registrant) will be made only upon delivery to the Registrant of an undertaking, by or on behalf of such officer or director, to repay all amounts so advanced if it is ultimately determined that such person is not entitled to be indemnified for such expenses under the Charter or otherwise.

The rights to indemnification and advancement of expenses will not be deemed exclusive of any other rights which any person covered by the Charter may have or hereafter acquire under law, the Charter, the Registrant's bylaws (the "Bylaws"), an agreement, vote of stockholders or disinterested directors, or otherwise.

Any repeal or amendment of provisions of the Charter affecting indemnification rights, whether by the Registrant's stockholders or by changes in law, or the adoption of any other provisions inconsistent therewith, will (unless otherwise required by law) be prospective only, except to the extent such amendment or change in law permits the Registrant to provide broader indemnification rights on a retroactive basis, and will not in any way diminish or adversely affect any right or protection existing at the time of such repeal or amendment or adoption of such inconsistent provision with respect to any act or omission occurring prior to such repeal or amendment or adoption of such inconsistent provision. The Charter also permits the Registrant, to the extent and in the manner authorized or permitted by law, to indemnify and to advance expenses to persons other than those specifically covered by the Charter.

The Bylaws include the provisions relating to advancement of expenses and indemnification rights consistent with those which are set forth in the Charter. In addition, the Bylaws provide for a right of indemnity to bring a suit in the event a claim for indemnification or advancement of expenses is not paid in full by the Registrant within a specified period of time. The Bylaws also permit the Registrant to purchase and maintain insurance, at the Registrant's expense, to protect it and/or any director, officer, employee or agent of the Registrant or another entity, trust, or other enterprise against any expense, liability, or loss, whether or not the Registrant would have the power to indemnify such person against such expense, liability, or loss under the DGCL.

Any repeal or amendment of provisions of the Bylaws affecting indemnification rights, whether by the Registrant's board of directors, stockholders or by changes in applicable law, or the adoption of any other provisions inconsistent therewith, will (unless otherwise required by law) be prospective only, except to the extent such amendment or change in law permits the Registrant to provide broader indemnification rights on a retroactive basis, and will not in any way diminish or adversely affect any right or protection existing thereunder with respect to any act or omission occurring prior to such repeal or amendment or adoption of such inconsistent provision.

The Registrant has entered into indemnification agreements with each of its officers and directors. These agreements require the Registrant to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Registrant, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Item 16. Exhibits.

The following documents are filed as exhibits to this registration statement, including those exhibits incorporated herein by reference to a prior filing under the Securities Act or the Exchange Act, as indicated in parentheses:

Exhibit Number	Description of Document
1.1	Form of Underwriting Agreement**
4.1	Specimen Common Stock Certificate**
4.2	Form of Preferred Share Certificate**
4.3	Form of Warrant**
4.4	Form of Warrant Agreement**
4.5	Form of Unit Agreement**
4.6	<u>Form of indenture with respect to senior debt securities, to be entered into between registrant and a trustee acceptable to the registrant, if any.</u> ⁽¹⁾
4.7	<u>Form of indenture with respect to subordinated debt securities, to be entered into between registrant and a trustee acceptable to the registrant, if any.</u> ⁽¹⁾
4.8	Form of debt securities, if any**
4.9	Form of Right Certificate, if any**
5.1	<u>Opinion of Hunter Taubman Fischer & Li LLC</u> ⁽¹⁾
23.1	<u>Consent of Marcum Asia CPAs LLP</u> *
23.2	<u>Consent of CBIZ CPAs P.C.</u> *
23.4	<u>Consent of Hunter Taubman Fischer & Li LLC (included in Exhibit 5.1)</u> ⁽¹⁾
24.1	<u>Power of Attorney (Included on signature page)</u> *
25.1	Statement of Eligibility of trustee on Form T-1 under the Trust Indenture Act of 1939 under the Senior Indenture+
25.2	Statement of Eligibility of trustee on Form T-1 under the Trust Indenture Act of 1939 under the Subordinated Indenture+
107	<u>Calculation of Filing Fee Table</u> ⁽¹⁾

* Filed herewith

** To be filed by amendment or as an exhibit to a filing with the SEC under Section 13 or 15(d) of the Securities Exchange Act of 1934 and incorporated by reference in connection with the offering of securities to the extent required for any such offering.

+ To be filed pursuant to Rule 305(b)(2) of the Trust Indenture Act, if applicable.

(1) Incorporated by reference to the Registration Statement on Form S-3 filed on August 28, 2026.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

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

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) (§ 230.424(b) of this chapter) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Filing Fee Tables" or "Calculation of Registration Fee" table, as applicable, in the effective registration statement.
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

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

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act (“Act”) in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.
- (7) That for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant’s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan’s annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (8) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, Niki BioSolutions, Inc. certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Princeton, New Jersey on September 18, 2026.

NIKI BIOSOLUTIONS, INC.

By: /s/ Ian Huen
Ian Huen
Chief Executive Officer

NIKI BIOSOLUTIONS, INC.

/s/ Ian Huen
Name: Ian Huen
Title: Acting Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

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

<u>/s/ Ian Huen</u> Ian Huen	Chief Executive Officer and Chairman of the Board of Directors	September 18, 2026
<u>/s/ Ian Huen</u> Ian Huen	Acting Chief Financial Officer	September 18, 2026
<u>/s/ Kira Sheinerman</u> Kira Sheinerman	Director	September 18, 2026
<u>/s/ Justin Wu</u> Justin Wu	Director	September 18, 2026
<u>/s/ Douglas Arner</u> Douglas Arner	Director	September 18, 2026
<u>/s/ Laura A. Philips</u> Laura A. Philips	Director	September 18, 2026



Independent Registered Public Accounting Firm's Consent

We consent to the use in this Registration Statement on Form S-3 of our report dated March 27, 2026 relating to the financial statements of Niki BioSolutions, Inc. (formerly known as Aptorum Group Limited) appearing in this Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Marcum Asia CPAs LLP

Guangzhou, China
September 18, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-3 of our report dated August 21, 2026 with respect to the financial statements of DiamiR Biosciences Corp. included in the Current Report on Form 8-K/A of Niki BioSolutions, Inc. dated August 21, 2026. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ CBIZ CPAs P.C.

New York, New York
September 18, 2026