OVERVIEW

We are a biotechnology company focused on and pioneering in the development and commercialization of molecular diagnostic instruments and biochips. Our product offerings include molecular diagnostic products and electrochemical long-read next-generation sequencing (EL-NGS) platform and biochips for multi-omics analysis.

Our Strategic Focus

Our immediate strategic focus is on the commercialization and further application development of our molecular diagnostics products based on our proprietary electrochemical biochip technology. In parallel, as part of our long-term strategy, we will continue to develop our EL-NGS platform with long-read sequencing capabilities. This strategy is driven by the market demands for technologies with faster speed, higher accuracy, and greater accessibility.

Molecular Diagnostics Products

The market potential for molecular diagnostic product is immense, driven by the increasing demand for multiplex, rapid, cost-effective, and integrated detection solutions. The molecular diagnostic solutions currently available or under development primarily utilize non-sequencing testing methods, comprising fluorescence *in situ* hybridization (FISH), PCR and gene chip. According to CIC, the global market of non-sequencing molecular testing reached US$9.8 billion in 2024, which is projected to grow to US$22.5 billion in 2033, representing a CAGR of 9.7%.

Traditional polymerase chain reaction (PCR) products, while highly sensitive and specific, and currently used in clinical settings in a large scale especially after pandemic, are generally limited to detecting a small number of targets simultaneously, lacks scalability, and often requires multiple processing steps and specialized infrastructure. Legacy NGS technologies, on the other hand, can provide comprehensive information across multiple targets but are often cost-prohibitive, time-consuming, and unsuitable for real-time applications. These unmet needs point to the market opportunity for developing innovative products featuring multiplex target detection, lower costs and accelerated testing cycles.

Therefore, we have developed AxiLona EL-100, a molecular diagnostic product based on electrochemical biochip technology. According to CIC, the global electrochemical multiplex PCR-microarray testing market increased from US$93.3 million in 2018 to US$397.6 million in 2024, and is projected to reach US$1,027.8 million in 2033 with a CAGR of 11.1%. China's electrochemical multiplex PCR-microarray testing market increased from US$1.3 million in 2018 to US$2.2 million in 2024, and is projected to reach US$56.4 million in 2033 with a CAGR of 43.6%. The U.S. electrochemical multiplex PCR-microarray testing market increased from US$23.3 million in 2018 to US$105.5 million in 2024, and is projected to reach US$292.6 million in 2033 with a CAGR of 8.2%. The EU electrochemical multiplex PCR-microarray testing market increased from US$12.7 million in 2018 to US$220.9 million in 2024, and is projected to reach US$448.5 million in 2033 with a CAGR of 12.0%. In 2024, the electrochemical multiplex PCR-microarray

testing market accounts for approximately 4.1% of the overall non-sequencing molecular testing markets globally, 0.1% in China, 6.7% in the U.S., and 3.8% in the EU.

AxiLona EL-100 is one of the few molecular diagnostic products in China capable of performing electrochemistry-based, multi-target, rapid, low-cost, and integrated detection of biomolecules. We have completed the clinical trial for AxiLona EL-100 and have received its registration approval from Jiangsu MPA in April 2025. According to the device registration specification approved by Jiangsu MPA, our EL-100 provides qualitative analysis of current signals from nucleic acid microarray chips for nucleic acid-based medical testing applications and does not perform absolute quantification of nucleic acid samples. These microarray chips are components of test kits, and AxiLona EL-100 must be used in conjunction with compatible test kits for any clinical or research use only applications. We also plan to expand the clinical applications of the AxiLona EL-100 by adding protein detection functionality to address the huge market potential of protein testing.

EL-NGS Platform

Gene sequencing has diverse and far-reaching applications. In clinical settings, it can be used for tumor detection, diagnosis of genetic disorders, and detection of infectious diseases. Beyond clinical applications, gene sequencing plays a vital role in scientific research, drug development, agriculture, food safety testing, public health monitoring, and forensic science. This represents a market with tremendous long-term growth potential. According to CIC, the global market size of high-throughput gene sequencing reached US$7.1 billion in 2024, and is expected to achieve US$21.9 billion in 2033, representing a CAGR of 13.2%.

However, mainstream next-generation sequencing (NGS) products currently fall short in meeting the demand for long-read sequencing that provides clearer and more comprehensive genetic information. Existing long-read sequencing technologies are hindered by challenges such as high error rates and elevated costs, limiting their widespread adoption and leaving significant unmet needs in both scientific research and clinical applications. At the same time, sequencing cost remains a critical factor determining the accessibility and scalability of sequencing technologies. Affordable and accurate sequencing solutions are necessary to unlock the full potential of genomic applications.

Addressing these challenges requires new approaches that combine the advantages of long-read sequencing with cost efficiency and high accuracy, paving the way for a new generation of sequencing technologies tailored to evolving market needs. We are developing AxiLona AXP-100, which, according to CIC, is the world's first EL-NGS gene sequencer. Our AxiLona AXP-100 utilizes semiconductor biochips and integrates technologies across multiple disciplines, including biochemistry, integrated circuits, microfluidics, AI, and bioinformatics, featuring a wide range of advantages including long-read, high accuracy, low cost, and fast sequencing. According to CIC, the global EL-NGS testing market is estimated to increase from US$0.0 billion in 2024 to US$0.5 billion in 2033, representing a CAGR of 91.8% between 2024 and 2033. China's EL-NGS testing market is estimated to increase from US$0.0 billion in 2024 to US$0.2 billion in

2033, representing a CAGR of 77.0% between 2024 and 2033. The U.S. and EU EL-NGS testing markets are estimated to increase from nil in 2024 to US$0.1 billion in 2033, respectively. In 2024, the EL-NGS testing market accounts for approximately 0.0% of the overall high-throughput gene sequencing market globally, 0.1% in China, and nil in the U.S. and the EU.

Expanding Offerings based on Foundational Technology

Building upon our foundational technologies, we also leverage our expertise to develop other products and services. These efforts currently include providing customized small molecule synthesis and high-throughput protein mutagenesis services in the synthetic biology domain. Also, we are advancing development of multi-omics detection solutions for multiplex protein marker detection and protein sequencing. In addition, our electrochemical detection technology allows us to develop non-invasive saliva glucose monitoring systems, which has received validation from an industry-leading research institution that have established formal R&D collaboration with us on such systems. Moreover, we have developed the AxiLona Library Preparation Robotic System that enables automated library preparation for eight samples simultaneously with exceptional precision, through a collaborative partnership with a specialized liquid handling module manufacturer who supplies the robotic components and corresponding consumables. We will continue to advance the automation and portability of our AxiLona Library Preparation Robotic System sequencing workflows.

Our Strategic Pipeline

The pipeline chart below summarizes the development status of our product candidates, all of which are in-house developed.

Product	Main Application	Market/Regulatory Authority	Category	Development Stage					Expected/Actual time for Completion of the Current Stage	Expected/ Actual Clinical Trial Start Time	Expected/ Actual Commercialization Approval Time
				Pre-clinical			Clinical Trial[2]	Approval			
				Design	Design Verification	Type Testing[1]					
Devices											
Microarray Analyzer AxiLona EL-100 ★	Nucleic Acid Detection	EU/EU — German Institute for Medical Documentation and Information	A						Q3 2023	/	Q3 2023
		China/Jiangsu MPA[4]	II						Q2 2025	Q3 2024	Q2 2025
		U.S./FDA	II						Q1 2026	Q2 2026	Q3 2027
	Nucleic Acid Detection & Protein Detection[3]	China/Jiangsu MPA[4]	II						Q1 2026	Q4 2026	Q4 2027
		U.S./FDA	II						Q1 2026	Q4 2026	Q4 2028
EL-NGS Gene Sequencer AxiLona AXP-100 ☆	Gene Sequencing	China/NMPA	III						Q4 2025	Q1 2026	Q4 2027
		U.S./FDA	III						Q2 2025	Q4 2026	Q4 2028
EL-NGS Gene Sequencer AxiLona AXP-1000	Gene Sequencing	China/NMPA	III						Q3 2026	Q2 2027	Q2 2029
		U.S./FDA	III						Q3 2026	Q2 2028	Q4 2030
Test Kits											
Test Kit for X-linked Monogenic Disorder[5]	Genetic Disease Detection — Fragile X syndrome	China/NMPA	III						Q4 2025	Q2 2026	Q4 2028
Test Kit for Pathogenic Microorganism[6]	Respiratory Multiplex testing	China/NMPA	III						Q2 2026	Q4 2026	Q2 2029
	Meningitis	China/NMPA	III						Q1 2026	Q3 2026	Q3 2028

★ Core Product ☆ Key Product

Abbreviations: Q1 means the first quarter; Q2 means the second quarter; Q3 means the third quarter; Q4 means the fourth quarter

Notes:

(1) For the FDA registration in the U.S., type testing refers to safety and performance testing.
(2) In the EU, Nucleic Acid Detection is regulated under the In Vitro Diagnostic Regulation (IVDR). Under the IVDR, Nucleic Acid Detection devices classified as Class A are exempt from the requirement for clinical trials.
(3) Although AxiLona EL-100 for nucleic acid detection and AxiLona EL-100 for both nucleic acid and protein detection differ in detection targets, reagent kits and software modules, they share the same hardware configuration and will be regulated as one product by Jiangsu MPA.
(4) According to the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》), as a Class II medical device, EL-100 is regulated by the Jiangsu MPA.
(5) Designed for use in conjunction with AxiLona AXP-100.
(6) Designed for use in conjunction with AxiLona EL-100.

AxiLona EL-100, our Core Product

AxiLona EL-100 is a molecular diagnostic product based on electrochemical biochip technology. It delivers improved performance over conventional PCR systems, featuring multiplex target detection through 54 addressable electrodes that enable simultaneous analysis (up to 54 targets subject to our applications), high sensitivity (with a detection limit as low as 100 copies/ml), a rapid testing cycle (<2 hours), and exceptional user-friendly flexibility. These features make it well-suited for scientific research supported by RUO test kits, and for clinical applications supported by developing test kits with regulatory approval or through other pathways, distinguishing it from competing molecular diagnostic products.

Appearance of AxiLona EL-100

AxiLona EL-100 was admitted into the Special Registration Procedures for Innovative Class II Medical Devices (commonly known as Green Path) by the Jiangsu MPA in June 2024. We completed its clinical trial in March 2025, and have received the Class II medical device registration certificate for AxiLona EL-100 from Jiangsu MPA in April 2025. This registration approves our microarray analyzer for the qualitative analysis of signals generated by nucleic acid microarray chips in support of nucleic acid-based medical testing applications, and is not intended for absolute quantification of nucleic acid samples. These microarray chips are components of test kits, and AxiLona EL-100 must be used in conjunction with compatible test kits for any clinical or research use only applications. We also received the CE marking for AxiLona EL-100 in July 2023.

In June 2024, EL-100 became eligible for expedited regulatory review under the Green Path channel by Jiangsu MPA. The Green Path is an elite program under which the NMPA or its local counterparts grants priority review and accelerated approval to medical device candidates which meet stringent innovation criteria, including self-developed and owned core intellectual property, internationally advanced technologies and clear clinical value, and being in an advanced development state. Based on the Innovative Medical Device Special Review and Approval Procedure (《創新醫療器械特別審查程序》), special review procedures shall apply to the examination of medical devices in the following circumstances: (i) the applicant legally owns the invention patent right of the core technology of the product in China through the technological innovation activities led by the applicant, or legally obtains the invention patent right or the right to use the same in China through an assignment in accordance with law, and the time between the application for the special review of innovative medical devices and the publication date

of the patent authorization shall not exceed five years. Alternatively, the patent administrative department of the State Council has disclosed the application for the invention patent of the core technology, and the Patent Search and Consultation Center of the State Intellectual Property Office has issued a search report stating the novelty and creativity of the core technology solution of the product; (ii) the applicant has completed the preliminary research of the product and owns the product prototype, the research process is true and under control, and the research data is complete and traceable; and (iii) the main working principle or mechanism of action of the product is the first of its kind in China. It is also required that the product performance or safety has fundamental improvement compared with similar products, its technology is at the international leading level, and the clinical application value is significant. Compared to peer products, EL-100 enables simultaneous detection of multiple targets at low cost and high speed, offering significant clinical value. Based on the above, Jiangsu MPA considers that EL-100 has demonstrated its fundamental improvement compared with similar products, technological innovation at an international leading level, and met the above-mentioned criteria under the Innovative Medical Device Special Review and Approval Procedure (《創新醫療器械特別審查程序》) to apply the special review procedures under the Green Path.

Based on the Innovative Medical Device Special Review and Approval Procedure (《創新醫療器械特別審查程序》), a key benefit of the Green Path status is that prior to the acceptance of the registration application and in the process of technical review, the Center for Medical Device Evaluation of Jiangsu MPA may assign designated personnel to provide timely guidance upon the developer's requests and discuss relevant technical issues with the developer. The developer can request for discussion with designated personnel of the Center for Medical Device Evaluation of Jiangsu MPA on the following issues: (i) substantive technical issues; (ii) substantive safety issues; (iii) clinical trial plan; (iv) periodic summary and evaluation of the results of clinical trials; and (v) other important issues that need to be discussed. Such discussions will be documented and referred to in the Jiangsu MPA's review of the registration application after the application is submitted.

On May 9, 2024, the Jiangsu MPA accepted the administrative license application for the registration of EL-100 as an innovative medical device submitted by Anxuyuan Wuxi (Application No.: 2024052010025). In June 2024, we received the "Notification of Review Decision for Innovative Medical Device Registration Application of Class II Medical Devices" (Notification No.: 20240031) from the Jiangsu MPA, marking that the product has officially entered the innovative product registration process.

We will be subject to ongoing regulations in terms of manufacturing, advertising, and promotion after the commercialization of EL-100. To our knowledge, the Jiangsu MPA has not imposed any additional pre- or post-market requirements on EL-100 or obligations on the marketing authorisation holder. We plan to further improve our quality management system, conduct continuous post-marketing research activities, carry out monitoring and re-evaluation of adverse events on a regular basis, and adopt an effective product recall policy to ensure customer safety and satisfaction. According to CIC, these ongoing regulatory obligations and reviews are industry norm for medical device companies, which we do not expect to have any material impacts on our business operations or affect the eligibility of EL-100 as a Core Product.

In our completed clinical trial, our AxiLona EL-100 has demonstrated excellent detection consistency with the control system (a commercially available real-time fluorescence quantitative PCR instrument and respiratory pathogen nucleic acid detection kit). This clinical trial demonstrates that the consistency rate for the positive samples between our AxiLona EL-100 as the test system and the control system was 100.00%, the consistency rate for the negative samples between our AxiLona EL-100 as the test system and the control system was 100.00%, and the overall consistency rate was 100.00%. The Kappa value was 1.0000 (>0.75), indicating excellent detection consistency between the test system and the control system.

As to functionality, in this clinical trial, each positive and negative quality control sample yielded qualified results, with no instances of quality control failure. Also, during operation, the device correctly identified microarray chips, displayed working status, reported and stored detection results, and functioned normally, demonstrating high stability. The microarray analyzer maintained continuous operation without abnormal operations. As to convenience of use, the average user rating is 98 (out of 100). Furthermore, no safety-related events occurred.

AxiLona AXP-100, our Key Product

AxiLona AXP-100 EL-NGS gene sequencer, the world's first EL-NGS platform, according to CIC, achieves an optimal balance across four critical metrics: accuracy (>99%), read length (single-molecule cyclic sequencing with repetitive consensus analysis based on simultaneous synthesis and sequencing), cost (significantly lower cost per Gigabases of data), and speed (up to one million reads concurrently). AxiLona AXP-100 can serve both clinical applications such as diagnoses of cancer and infectious disease and scientific research needs including structural variations study, and single-gene disease investigation.

Appearance of AxiLona AXP-100

We launched the product prototype of AxiLona AXP-100 in 2021, and launched it for research use in 2023. We also plan to actively pursue the clinical application of AxiLona AXP-100. We expect to complete the type testing for AxiLona AXP-100 in the second half of 2025 in China and subsequently initiate a clinical trial for AxiLona AXP-100, after which we will pursue regulatory registration based on the trial outcomes.

AxiLona AXP-1000

We plan to develop AxiLona AXP-1000, which would feature a higher throughput sequencing chip with ten million nanopore channels, offering nearly ten times the throughput of the AxiLona AXP-100. AxiLona AXP-1000 is currently in the design phase and we expect to complete the design of AxiLona AXP-1000 in the second half of 2026.

Test Kits

Our test kits comprise biochips, reagents and other necessary consumables. We are currently developing test kits for both of our molecular diagnostic products and EL-NGS platform. For example, we have been actively advancing development of specialized test kits for genetic disease detection and pathogenic microorganism detection. We anticipate completing design verification of the genetic disease detection test kits in the second half of 2025, and expect the pathogenic microorganism detection test kits targeting bacteria, viruses, and fungi to complete the design verification in the first half of 2026.

Other Product and Service Offerings

One of our key offerings extended based on our foundational technology is custom synthesis of chemical products, which involves tailored small molecule synthesis, optimization, and enhancement of biological activity. This service has been fully developed, and we have already delivered two batches of products to clients in 2024. Another fully developed service we offer is high-throughput protein mutagenesis services, which typically includes gene synthesis, mutant library construction, protein expression and purification, high-throughput screening of mutants, and sequence validation.

We are also developing service solutions for multi-omics protein detection. These potential offerings include our ELP solution for multiplex protein marker detection built on the EL-100 platform and our AXPP solution for protein sequencing based on our EL-NGS platform. The development of these solutions is part of our long-term strategy to extend our core platform capabilities.

In addition, we have developed a consumer-focused non-invasive saliva glucose monitor for home-use point-of-care testing (POCT). This saliva-based blood glucose monitoring solution enables users to obtain clinical-grade glucose readings through simple oral fluid collection, eliminating traditional blood sampling requirements. Notably, we have entered into a collaboration arrangement with an industry-leading research institution for further development, demonstrating market validation of both our technology and R&D competencies.

The AxiLona Library Preparation Robotic System, a next-generation robotic platform for genomic workflow automation, represents our efforts to further expand product portfolio. The system combines industrial-grade robotic liquid handling, which achieves microliter-scale precision and enables the simultaneous processing of eight samples. Based on our internal testing, this system has demonstrated the potential to reduce processing time by approximately 50% compared to manual methods, while

maintaining consistent library quality and yield. This robotic platform has already been integrated into our testing workflows, contributing to improved operational efficiency and consistency. Through a collaboration with a specialized liquid handling module manufacturer, we are incorporating high-quality robotic components and corresponding consumables into this system. We will enjoy the ownership of the patents related to such robotic system developed through the current partnership mode. In the future, we may forge additional partnerships with other industry players or suppliers to further enhance the automation and portability of sequencing workflows of our AxiLona Library Preparation Robotic System.

Our Journey and Strategic Evolution

Since our inception, our focus has been on the research and development of our foundational electrochemical detection technology and proprietary semiconductor biochips. Our initial vision was to create a versatile platform capable of detecting a wide range of substances, including nucleic acids, proteins, and small molecules.

The development journey for our core molecular diagnostics product, AxiLona EL-100, began in 2018 with the initial principle design. By October 2019, we had finalized the core detection solution, encompassing electrode modification, electrochemical detection methods, and sample preparation protocols. We released our first-generation electrochemical chip and a corresponding engineering prototype microarray analyzer in April 2020. A key milestone was achieved in November 2021 when we completed full system testing for pathogen detection application on our product prototype. In November 2022, we launched our second-generation electrochemical chip and microfluidic cassette, which significantly reduced costs and brought the technology to a level suitable for clinical applications.

This technological maturation informed our strategic decision to prioritize the commercialization of our molecular diagnostics product, AxiLona EL-100. This product utilizes a robust and mature hybridization-based biochemical methodology, enabling a more rapid development and clinical validation pathway compared to the more complex sequencing-by-synthesis biochemistry required for our EL-NGS platform. This strategic prioritization allows us to enter the clinical market sooner while we continue the long-term development of our EL-NGS platform, AxiLona AXP-100, for the research market and future clinical applications.

Our Technology Platforms

We focus on developing innovative life science technology platforms, with core expertise spanning four key areas: integrated circuit chips, synthetic biology and chemical engineering, electrochemistry and microfluidics, and artificial intelligence.

Integrated Circuit Chip Technology

Our semiconductor Bio-CMOS chip technology revolutionizes gene sequencing and molecular diagnostics. Designed using complementary metal oxide semiconductor (CMOS) principles and a 300mm, 65-nm fabrication process, these chips achieve highest

density through unmatched high-throughput performance with over one million parallel nanopore detection cells per chip (with completed design of next generation chip scaling to tens of millions), reducing sequencing costs significantly. The chip's precision is enhanced by alternating current (AC) impedance detection and lab-on-chip microfluidics, which minimizes noise and boosts accuracy. Furthermore, its compatibility with standard semiconductor processes enables scaled mass production at reduced costs, creating a strong competitive edge. This proprietary technology positions us as a key player in the integration of semiconductor innovation with life sciences applications.

Synthetic Biology and Chemical Engineering

Our synthetic biology and chemical engineering platform is a cornerstone of our technological capabilities. Equipped with state-of-the-art synthesis and analytical tools, this platform supports high-purity (HPLC main peak area ≥ 98% after purification, MS (mass spectrometry) purity ≥ 95%), customized synthesis of DNA, RNA, phosphoramidites, oligonucleotides, and modified dNTP biomarkers at batch capacities up to 1 mmol. These innovations enhance the signal-to-noise ratio in sequencing applications, improving data quality. Additionally, our AI-assisted enzyme engineering capabilities, including microfluidics-based high-throughput protein screening (10^5–10^6 mutants) and rational design systems, have led to the discovery of salt-tolerant, high-performance polymerases that drive the performance of our sequencing products. This comprehensive platform ensures we deliver solutions for the most demanding molecular biology challenges.

Electrochemical and Microfluidic Integration

Our Bio-CMOS chip's integration of electrochemical biosensing and microfluidic precision delivers transformative benefits for gene sequencing and molecular diagnostics. This technology enables ultra-low-cost instruments and test kits, high-density detection arrays with unparalleled sensitivity, accuracy, and speed. By eliminating bulky optical components, our approach paves the way for miniaturized, portable and compact sequencing devices, making diagnostics more accessible. With its fast turnaround times and scalability, our electrochemical and microfluidic platform is setting a new standard for cost-effective and efficient molecular detection solutions, addressing a wide range of applications.

Our AI-Driven Innovation

AI is at the core of our efforts in technological advancement, driving progress across multiple areas of our platform, including enzyme screening and engineering, product design and optimization, as well as data and bioinformatics analysis.

AI-assisted Enzyme Engineering and Protein Screening and Modification

Currently, the detection of AxiLona EL-100 process employs PCR polymerase, while the EL-NGS sequencing process makes use of polymerase. The performance of these enzymes is critical to the success of our products. AI plays an important part in our screening and engineering of enzymes, driving breakthroughs in precision and efficiency. Leveraging our expertise in synthetic biology and protein engineering, AI unlocks

immense opportunities for the design and optimization of polymerases, nanopore proteins, and sequencing complexes. Through AI-supported structural simulations and in-depth analyses, we can identify critical sites and refine enzyme modeling to achieve superior performance. Additionally, AI enables the development of microfluidics-based high-throughput protein mutation systems, further enhancing our capabilities. We have already established targeted gene mutation libraries using microfluidics-based PCR, facilitating protein-directed evolution through Compartmentalized Self-Replication. By integrating high-throughput screening results with AI-assisted rational design methodologies, our platform achieves high precision and efficiency in protein screening and modification. These advancements not only enhance the capabilities of our existing platforms but also expand our ability to provide comprehensive solutions in this domain.

Enrich Offerings with AI: AI-enhanced Data Generation and Bioinformatics Analysis

Our AI-assisted multiplex panel design for AxiLona EL-100 integrates machine learning with multiple bioinformatics alignment algorithms to identify highly specific primer-probe binding sites, optimize physical and chemical parameters, and perform specificity validation. Leveraging existing PCR/qPCR datasets to train predictive models, the system estimates amplification efficiency, assesses dimerization risk, enables multi-objective optimization, and detects aberrant sequence that may compromise amplification performance.

Our R&D, Manufacturing and Commercialization Capabilities

At the core of our competitive edge lies our robust in-house R&D capabilities, underpinned by a sophisticated R&D infrastructure that drives continuous advancement and iteration of our product portfolio. As a life sciences company founded in the U.S. and grown in China, we have been actively pursuing a multi-national strategy. Over the years, we have strategically established four R&D centers across Silicon Valley, Shenzhen, Tianjin, and Wuxi, each equipped with sophisticated experimental facilities to fuel our R&D endeavors. As of the Latest Practicable Date, our sophisticated and stable R&D team comprised 75 members with multidisciplinary backgrounds and industry know-how across semiconductor, biotechnology and artificial intelligence, approximately 60% of whom hold doctorate or master's degrees. Globally, our founders have secured over a hundred issued patents, with several more under application.

We have established the first GMP-compliant manufacturing facility in Wuxi, Jiangsu Province, which spans a site area of approximately 4,100 sq.m. This facility is designed to support the demands for our instruments and their exclusively compatible test kits. We have received the medical device production permit for AxiLona EL-100 from Jiangsu MPA in April 2025. We are also accelerating our path to commercialization and have already developed a network of partners and clients who are trialing our product candidates. These initiatives are anticipated to raise awareness about our products, paving the way for future market acceptance once they commercially scale up.

COMPETITIVE STRENGTHS

We are a frontrunner in integrated circuit biotechnology, specializing in the development of sophisticated life science tools, including molecular diagnostics products and electrochemical long-read next-generation sequencing (EL-NGS) platform, offering multi-omics solutions for life science research and clinical applications

We are a frontrunner in integrated circuit biotechnology, specializing in developing specialist tools that drive innovation in life science sector. We specialize in molecular diagnostics product designed to provide rapid, reliable results in a wide range of clinical settings. Our portfolio includes EL-NGS platform, which delivers unparalleled accuracy and scalability for comprehensive genomic analysis. We are also actively expanding the boundaries of innovation in other products and services based on our foundational technology. Aiming to provide integrated multi-omics solutions, we are committed to empowering researchers and clinicians to address complex challenges, accelerate breakthroughs, and advance diverse applications in life sciences and clinical practice.

Molecular diagnostics products

The non-sequencing molecular testing market demands innovation for multiplex, rapid, cost-effective, and integrated detection solutions to address critical unmet needs. Our Core Product AxiLona EL-100 directly answers this market call. Compared to traditional molecular diagnostic technologies such as fluorescence PCR, our AxiLona EL-100 exhibits distinct technical advantages offered by advanced biochip technology, including higher-throughput gene expression profiling, superior genome-wide screening and enhanced cost-effectiveness for whole genome studies. Our AxiLona EL-100 strategically delivers improved performance over conventional PCR systems, featuring multiplex detection capability through 54 addressable electrodes that enable simultaneous analysis (up to 54 targets subject to our applications), high sensitivity (detection limit as low as 100 copies/ml), accelerated testing cycles (under 2 hours), and superior operational flexibility. This comprehensive performance profile positions our Core Product optimally for both research environments and clinical applications, establishing clear differentiation in the competitive landscape.

AxiLona EL-100 was admitted into the Special Registration Procedures for Innovative Class II Medical Devices (commonly known as Green Path) by the Jiangsu MPA in June 2024. We completed its clinical trial in March 2025. In this clinical trial, our AxiLona EL-100 has demonstrated excellent detection consistency with the control system (a commercially available real-time fluorescence quantitative PCR instrument and respiratory pathogen nucleic acid detection kit). The consistency rate for the positive samples between AxiLona EL-100 and the control system was 100.00%, the consistency rate for the negative samples between AxiLona EL-100 and the control system was 100.00%, and the overall consistency rate was 100.00%. The Kappa value was 1.0000 (>0.75), indicating excellent detection consistency between the test system and the control system. It has also demonstrated high quality control, stability and user convenience in this clinical trial, with no safety-related events reported. We have received the registration approval for AxiLona EL-100 from the Jiangsu MPA in April 2025. This registration

approves our microarray analyzer for the qualitative analysis of signals generated by nucleic acid microarray chips in support of nucleic acid-based medical testing applications, and is not intended for absolute quantification of nucleic acid samples. These microarray chips are components of test kits, and AxiLona EL-100 must be used in conjunction with compatible test kits for any clinical or research use only applications. We also received the CE marking for AxiLona EL-100 in July 2023.

EL-NGS platform

Despite significant development in the field, current mainstream next-generation sequencing (NGS) platforms exhibit substantial limitations in addressing the growing requirement for long-read sequencing capabilities — an evolving technology that delivers more comprehensive and clearer genetic insights. However, existing long-read sequencing technologies face persistent challenges in error reduction and cost efficiency that have limited their wide use. Our AxiLona AXP-100 has emerged as the world's first EL-NGS gene sequencer, according to CIC, combining semiconductor biochips with technologies across different scientific fields to solve the industry challenges. We have launched AxiLona AXP-100 for research use in 2023 and will actively pursue its clinical development. It achieves an optimal balance across four critical metrics: read length, accuracy, cost and speed.

- **Groundbreaking long-read sequencing with high precision.** By introducing the groundbreaking EL-NGS using proprietary polymerases and molecular tags, AxiLona AXP-100 enables simultaneous synthesis and sequencing. This technology allows for single-molecule cyclic sequencing with repetitive consensus analysis, ensuring long reads, high precision, and real-time sequencing and data output.

- **Superior efficiency with low costs enabled by proprietary semiconductor technology.** Leveraging proprietary semiconductor technology, we have developed an ultra-low-cost yet effective sequencing platform. Our proprietary Bio-CMOS sequencing chip is the globally first 300mm, 65nm process Bio-CMOS chip with one million sequencing channels. With over one million parallel nanopore detection units per chip with AC impedance detection design, this ultra-high throughput design significantly reduces sequencing costs, creating a sequencing platform with unprecedented affordability while providing enhanced stability and faster data generation.

- **Reduced production costs.** We have successfully achieved lower production costs for Bio-CMOS sequencing chip with the highest sequencing channel density. We aim to achieve its large-scale production to further reduce the product costs and enable accessible enhanced applications such as protein sequencing.

Extended product and service offerings

Our technology platforms allow us to broaden our product and service portfolio across the biotechnology value chain. For services, highlights include customized small molecule synthesis and high-throughput protein mutagenesis in synthetic biology, and advancements in multi-omics protein detection solutions. Also, we are actively exploring development of other new products such as development of non-invasive saliva glucose monitor and AxiLona Library Preparation Robotic System for automated, high-precision sample processing.

We focus on developing foundational platforms, with core expertise spanning four key areas: integrated circuit chips, synthetic biology and chemical engineering, electrochemistry and microfluidics, and artificial intelligence. The integration of IC (integrated circuits), BT (biotechnology), and AI (artificial intelligence) creates a uniquely distinctive position for us in the industry

By seamlessly integrating IC (integrated circuits), BT (biotechnology), and AI (artificial intelligence), we have established a uniquely distinctive position in the industry. These diverse yet complementary areas of expertise enable us to create new and robust technological solutions that address complex challenges. Building on this foundation, we continuously leverage these technologies to develop a growing portfolio of new products and expand service offerings.

Integrated Circuit Chip Technology

Our semiconductor biochips are the core components of gene sequencers and other molecular diagnostic products. The technological leadership of these chips further drives the high throughput, low cost, and high accuracy of sequencing and molecular diagnostics.

According to CIC, we are among the few companies in the molecular testing industry with a semiconductor R&D team, who possess extensive experience in advanced semiconductor process design and manufacturing focused on integration with bio liquids. Our chips are engineered based on traditional CMOS principles to enable multi-array scanning, the generation and reading of various electrochemical signals with a very low noise, and enabling high-speed analog-to-digital conversion on a large scale but using lab-on-chip microfluidics. By adopting an AC-based design, the size of each working cell is much smaller than that of direct current (DC)-based designs, allowing for higher energy integration on a single chip and making production easier using existing integrated circuit processes.

We have successfully developed the worlds' first 300mm, 65nm process Bio-CMOS chip with over one million parallel nanopore detection cells per chip. It has successfully undergone mass production and device validation, significantly reducing detection costs. Bio-CMOS chip is currently used in AxiLona platform, and is expected to be included in our multiple clinical and pre-clinical stage product candidates.

Synthetic Biology and Chemical Engineering Technology

We have developed a proprietary synthetic platform, which enables the synthesis and modification of sequencing-related molecules, and ensures the stable delivery of high-quality products. The synthesis platform is equipped with comprehensive synthesis and analytical instruments, capable of performing small molecule building block synthesis, post-synthetic modification, preparation and purification, as well as analytical testing. This platform supports diverse synthesis applications, including standard DNA/RNA, modified DNA/RNA, modified nucleobases, and customized categories. It offers high synthesis capacity (maximum single-run synthesis up to 1 mmol) and high product purity (HPLC main peak area ≥ 98% after purification, MS purity ≥ 95%).

Furthermore, combining high-throughput protein screening based on microfluidics with AI-assisted rational protein design, we have established a foundational enzyme engineering technology platform. Our high-throughput protein screening platform can efficiently screen approximately 10^5 to 10^6 random mutants, while AI-assisted rational protein design enables sequence and key site analysis. The combination of these approaches forms our foundational enzyme engineering technology platform, which can be applied to scenarios such as protein function modification to enhance biological performance, or to synthetic biology for increasing the yield of bio-based compounds.

Electrochemistry and Microfluidics Technology

Our biochips combine electrochemical biosensor technology with precision microfluidic systems, significantly improving detection efficiency, lowering costs, and enabling compact, portable designs. These technologies are seamlessly integrated into our gene sequencers and molecular diagnostic products. Compared to optical signal detection methods, electrochemical detection delivers substantial cost advantages. Furthermore, the AC-based design minimizes equipment size and further reduces costs. Beyond gene sequencing, electrochemical and microfluidic technologies are adaptable to a variety of applications, including non-invasive saliva glucose monitoring and rapid multiplexed biomarkers detection.

AI-Driven Innovation

Our AI capabilities enhance our ability in synthetic technology and chemical engineering. For example, AI supported our design and optimization of polymerases, nanopore proteins, and sequencing complexes. Utilizing AI-supported structural simulations and detailed analyses, we can identify key sites and improve enzyme modeling to deliver superior performance. Moreover, AI facilitates our development of microfluidics-based high-throughput protein mutation systems. We have also successfully established targeted gene mutation libraries through microfluidics-based PCR, enabling protein-directed evolution via Compartmentalized Self-Replication. By combining high-throughput screening data with AI-assisted rational design techniques, our platform achieves exceptional accuracy and efficiency in protein screening and modification. Our AI capabilities not only boost the effectiveness of our existing platforms but also broaden our ability to offer comprehensive solutions in this field.

Apart from empowering our synthetic biology and chemical engineering, AI is also transforming how we design and optimize our products. By leveraging deep learning

structures, we have developed proprietary technologies that can significantly enhance the accuracy of gene sequencing, molecular diagnostics, and metagenomic assembly through our capabilities like our patented sequence correction methods and the MetaCONNET tool (a novel deep-learning polishing tool for polishing metagenomic assemblies). Moreover, our AI-informed diagnostic solutions can analyze comprehensive health data to generate predictive insights that inform personalized longevity strategies, positioning our company at the forefront of the rapidly expanding proactive healthcare market with multiple commercialization pathways. By integrating AI, we aim to develop diagnostic solutions that deliver personalized wellness and longevity analyses and actionable insights, unlocking new possibilities in sequencing applications and healthcare services.

In addition, the integration of AI algorithms into bioinformatics is revolutionizing the analysis of complex biological data, and we are at the forefront of leveraging this technology to enhance efficiency and accuracy. Our genomic data acts as the essential foundation of our technology, bringing together sequencing results and organized information from multiple sources to power our AI learning systems. This centralized knowledge hub transforms complex genetic information into actionable insights that continuously strengthen our analytical capabilities. Our AI-enhanced bioinformatics solutions are widely applied across various scenarios, such as circular consensus sequence correction, metagenomic assembly error correction, and longevity-focused diagnostic solutions.

Robust and efficient R&D framework dedicated to fostering innovation and driving transformation

At the core of our competitive edge lies our robust in-house R&D capabilities, underpinned by a sophisticated R&D infrastructure that drives continuous advancement and iteration of our product portfolio. Over the years, we have strategically established four R&D centers across Silicon Valley, Shenzhen, Tianjin, and Wuxi, each equipped with sophisticated experimental facilities to fuel our R&D endeavors. Notably, we boast a highly skilled and multidisciplinary R&D team, which comprises a staggering 63% of our total workforce. Approximately 60% of these team members hold a master's or higher degree, and their expertise spans an array of specialized fields including, without limitation, integrated circuits, biochemistry, organic chemistry, surface physics, microfluidics, physical chemistry, bioinformatics, big data, and artificial intelligence. Globally, our founders have secured nearly a hundred issued patents, with several more under application.

We place great emphasis on independent R&D initiatives, and our technological prowess is further validated by a well-structured global intellectual property portfolio. As of the Latest Practicable Date, we owned an aggregate of 53 issued patents in China, the U.S., and other jurisdictions, as well as 17 software copyrights and four layout-design of integrated circuits registered in China, which collectively safeguard our proprietary products and technologies.

Our achievements in R&D are inseparable from a seasoned and visionary leadership team composed of industry veterans. Dr. Tian, our founder and CEO, brings a robust academic foundation complemented by over 100 issued patents globally as an inventor

and over 20 years of industry experience in biotechnology and semiconductor. Dr. Ivanov, our founder and COO, holds an impressive track record of innovation, with over 100 issued patents as an inventor and numerous peer-reviewed publications to his name. Together, they bring a synergy of expertise, vision, and leadership that propels our innovation and shapes our growth trajectory.

In recognition of our R&D capabilities, we are the partner of choice with a number of globally renowned universities, research institutes, and biotechnology companies. We are actively fostering industry-academia collaborations, as exemplified by our collaboration on development of non-invasive saliva glucose monitor with an industry-leading research institute. We became an NVIDIA Inception Member in 2023, which allows us to leverage NVIDIA's cutting-edge technologies and open collaborative ecosystem to advance and promote the gene sequencing technology. We have also earned acknowledgement in the entrepreneurial and innovation sector, particularly by advancing to the finals of the inaugural Artificial Intelligence Challenge in the 2024 Nanshan "Entrepreneurship Star" competition.

Integrated manufacturing and commercialization capabilities with a strategic and forward-looking outlook

We are making significant strides in advancing our technology platform and a range of sophisticated life science tools. Our efforts focus on facilitating seamless transition across the biotechnology value chain, from groundbreaking research to industrial applications, and from laboratory to clinical settings. This strategic approach not only underscores our commitment to bridging scientific discovery with practical healthcare solutions, but also the viability of our business model in translating R&D achievements into tangible commercial success.

We have established the first GMP-compliant manufacturing facility in Wuxi, Jiangsu Province, which spans a site area of approximately 4,100 sq.m. This facility is designed to support the demands for our instruments and their exclusively compatible test kits. We have received the medical device production permit for AxiLona EL-100 from Jiangsu MPA in April 2025. We are also accelerating our path to commercialization and have already developed a network of partners and clients who are trialing our product candidates. These initiatives are anticipated to raise awareness about our products, paving the way for future market acceptance once they are officially launched.

As a life sciences company founded in the U.S. and grown in China, we have been actively pursuing a multi-national strategy. We have built an R&D center in the U.S., staffed by a dedicated overseas R&D team of experience professionals. We hold 13 issued overseas patents, with the majority of our patent portfolio protected globally. We have also reached collaborations with prestigious institutions such as Brown University and various overseas laboratories and testing centers, driving the global development and deployment of our products, particularly the EL-NGS platform. Additionally, we are expanding our commercial presence on a global scale, and may build sales and distribution channels in major international markets, as well as fostering international commercial partnerships. We believe this adaptive global expansion strategy will enable us to rapidly tap into regions with high demand for our proprietary products, enhancing market penetration and brand visibility.

A seasoned management team with interdisciplinary scientific expertise and deep industry insight

We are led by a seasoned management team with proven track record. Our founder and CEO, Dr. Tian, is a leading scientist who is the inventor of over 100 granted patents globally, with more than 20 years of experience in the fusion of biotechnology and semiconductor. Dr. Tian obtained a bachelor's degree in applied physics with a minor in business management and a master's degree in engineering physics from Tsinghua University (清華大學) in the PRC in July 1993 and July 1996, respectively. He also obtained a master's degree in electrical engineering and a PhD degree in applied physics from Stanford University in the United States in January 1999 and September 2000, respectively. Before founding our Group, Dr. Tian served leadership roles at global pharmaceutical multinational company, and Silicon Valley technology companies such as InVisage Technologies Inc. (a fabless semiconductor pioneer acquired by Apple Inc. in 2017 and known for QuantumFilm, a quantum dot-based image sensor technology) and Aptina, positioning him as a pioneer in the convergence of biotechnology and semiconductor technology. Our founder and COO, Dr. Ivanov, is a successful serial entrepreneur with over 30 years of experience in semiconductor and technology industries. As an inventor of over 100 granted patents globally, his expertise in nanomaterials and semiconductor, honed through previous career at InVisage Technologies Inc., Intermolecular (an advanced material innovation company which later went public on Nasdaq and subsequently acquired by Merck KGaA.), Blue29, CuTek and Mattson, provide valuable insights into our technological advancements and potential commercial success.

Under Dr. Tian and Dr. Ivanov's leadership, we have assembled a visionary and insightful scientist-led management team, consisting of multiple serial entrepreneurs, executives from multinational corporations, engineers and scientists. Our management team have educational backgrounds from prestigious international universities, and extensive professional experience at various leading multinational enterprises and research organizations. Their comprehensive expertise across different key areas encompasses gene sequencing, molecular diagnostics, IC design, hardware development, software development, product commercialization, and business development. Their diverse, interdisciplinary expertise empowers us to address the complex challenges at the intersection of IC (integrated circuits), BT (biotechnology), and AI (artificial intelligence).

STRATEGIES

Accelerate the development of our product portfolio to solidify our competitive edge in molecular diagnostics products and EL-NGS gene sequencing

We have developed a robust product portfolio in molecular diagnostics and gene sequencing. Moving forward, we aim to accelerate product development across all stages, from preclinical studies all the way to research and clinical applications. Additionally, we are committed to advancing research and development efforts to introduce upgraded products and expand their range of applications. Specifically, we plan to prioritize the following product developments:

AxiLona EL-100

We plan to advance clinical development of AxiLona EL-100 in the U.S., and expect to complete its safety and performance testing in the first half of 2026, following which we will proceed with the clinical trial upon receiving the approval. We plan to upgrade AxiLona EL-100 to enable both nucleic acid detection and protein detection. We plan to upgrade AxiLona EL-100 to enable both nucleic acid detection and protein detection. According to the consultations conducted by our legal advisors as to PRC laws with the regulatory authority Jiangsu MPA in April 2025, the addition of new protein detection functionality constitutes a registration variation matter rather than development of a new product, which will be covered under the same medical device registration certificate. This feature will be applicable in various clinical fields, including the detection of specific protein biomarkers related to Alzheimer's disease, aiding in its diagnosis. We expect to complete the design of protein detecting function in the first quarter of 2026.

We also plan to continue exploring its potentials in overseas markets. We received the EU CE marking for AxiLona EL-100 in July 2023, and expect to strategically expand its global presence through collaboration with local partners.

According to the Medical Device Product Classification Determination Notice issued by the NMPA, our AxiLona EL-100, which features nucleic acid detection capabilities, has been classified as a Class II medical device. We have already obtained the corresponding Class II medical device registration certificate. We anticipate that AxiLona EL-100 will remain classified as Class II, based on its intended use, references to existing market products, and consultations conducted by our PRC Legal Advisors with Jiangsu MPA in April 2025. In the European Union, we have secured the relevant certification for AxiLona EL-100 under the *In Vitro* Diagnostic Regulation (IVDR), which is classified as a Class A *in vitro* diagnostic medical device. We do not plan to pursue clinical registration for dual nucleic acid and protein detection functionalities in the European Union in the near term. Consequently, we do not anticipate any reclassification in the European Union, as long as no significant changes occur in the regulatory framework. In the U.S., a *De Novo* classification request refers to a marketing pathway to classify novel medical devices for which no legally marketed predicate device exists that could demonstrate substantial equivalence to the proposed device under the 510(k) pathway. Since we plan to pursue a 510(k) submission for AxiLona EL-100, according to the guidance issued by the FDA, a *De Novo* request can then only be submitted after receiving a "not substantially equivalent" determination. We are working with a CRO on the initial preparation of materials related to 510(k) requirements and have preliminarily identified a potential predicate device that could establish substantial equivalence, which has also undergone a clinical trial. Given the characteristics of AxiLona EL-100 and its planned regulatory pathway, we anticipate that the FDA is less likely to reclassify it as Class III or impose more stringent regulatory requirements. However, potential changes in applicable laws and regulations or unanticipated actions by regulatory authorities could result in reclassification of our product or the imposition of more rigorous approval procedures. Our Board of Directors is

of the view that the likelihood of the Company's products being reclassified in China, the United States, and Europe is unlikely. Based on the above, nothing has come to the attention of the Joint Sponsors that would cause them to disagree with the Board of Directors' view above.

AxiLona AXP-100

We plan to actively pursue the clinical application of our EL-NGS gene sequencer AxiLona AXP-100. We expect to complete the type testing for AxiLona AXP-100 in the second half of 2025 in China and subsequently initiate a clinical trial for AxiLona AXP-100, after which we will pursue regulatory registration based on the trial outcomes.

We will continuously iterate and upgrade the AxiLona AXP-100 to enhance its capabilities and performance. Specifically, we plan to continuously optimize biochemical performance, enhance sequencing accuracy, establish multi-chip parallel processing capabilities, improve throughput, shorten detection process time, and reduce device size.

In addition, we plan to develop AxiLona AXP-1000, which would feature a higher throughput sequencing chip with ten million nanopore channels, offering nearly ten times the throughput of the AxiLona AXP-100. AxiLona AXP-1000 is currently in the design phase and we expect to complete the design of AxiLona AXP-1000 in the second half of 2026.

AxiLona Library Preparation Robotic System

We have established a collaboration with a manufacturer with extensive liquid handling module development who will supply the robotic components and corresponding consumables under the relevant contract terms to us. Looking ahead, we may establish additional partnerships with other industry players or suppliers to further enhance the automation and portability of our AxiLona Library Preparation Robotic System sequencing workflows.

Test Kits

We are progressing the development of test kits for both of our molecular diagnostic products and EL-NGS platform. We plan to continue advancing development of specialized test kits for genetic disease detection and pathogenic microorganism detection. We anticipate completing design verification of the genetic disease detection test kits in the second half of 2025, and expect the pathogenic microorganism detection test kits targeting bacteria, viruses, and fungi to complete the design verification in the first half of 2026.

Expand and strengthen our core technology platform to further solidify our unique integration of IC (integrated circuits), BT (biotechnology), and AI (artificial intelligence)

Our strategy focuses on enhancing and broadening our core technology platform, which is built upon our expertise across four pivotal domains: semiconductor technology, synthetic biology and chemical engineering, electrochemistry and microfluidics, and artificial intelligence. These core competencies enable us to pioneer innovations at the

intersection of IC (integrated circuits), BT (biotechnology), and AI (artificial intelligence). By continually advancing our technological capabilities, we aim to strengthen this distinctive integration, unlocking new possibilities for solutions in both clinical and research applications. This commitment ensures that we remain at the forefront of scientific and technological convergence, addressing complex challenges with unparalleled precision and efficiency. We will continue to strengthen our IC and BT platforms through sustained R&D efforts and advancement. Leveraging the foundation of our IC and BT platform development, we are strategically accelerating our AI capabilities to continuously enhance our operational effectiveness, elevate customer experience, and extract maximum commercial value across our entire ecosystem. Building upon the technologies incubated within these platforms, we plan to progressively expand the boundaries of our product and service offerings to maximize the commercial value of our technology platforms.

Build up domestic and international commercialization capabilities to drive the successive commercialization of our product pipeline

We will continue to strengthen our in-house commercialization team and implement tailored strategies to meet the diverse demands of different application markets, including scientific research, clinical diagnostics, customs and disease control, translational medicine, and industrial sectors such as sequencing service providers. Our core sales strategy will focus on direct sales, allowing us to build strong customer relationships and deliver customized solutions. In parallel, we plan to establish a distributor network to penetrate specific market segments, leveraging local partnerships to enhance accessibility and expand our reach. By combining a specialized, market-focused commercialization team with a strategic mix of direct sales and distributor networks, we aim to maximize our market presence and drive the successful commercialization of our products.

We are actively preparing for the commercial launch of AxiLona EL-100 for clinical applications, and AxiLona AXP-100 for research applications in the future. We will adopt a dual approach that combines endorsements from Key Opinion Leaders (KOLs) with market-focused education initiatives. KOL endorsements will help establish credibility and trust within the industry and among potential customers, while educational efforts will raise awareness, enhance understanding, and highlight the value of our technologies and solutions to a broader audience. Additionally, we aim to create an open and collaborative platform by establishing strategic partnerships with leading industry players and benchmark institutions. These partnerships will not only amplify our market presence but also foster innovation and shared growth, positioning us as a key player in the industry.

While establishing our domestic market presence, we plan to explore market expansions in overseas markets, targeting key regions such as the United States and the European Union. In the United States, we plan to finish the type testing of our AxiLona EL-100 in nucleic acid detection in the first quarter of 2026 and initiate clinical trial in the second quarter of 2026. We also plan to finish the design of the upgraded version of AxiLona EL-100 that covers both nucleic acid detection and protein detection in the first quarter of 2026, and initiate clinical trial in the fourth quarter of 2026. We also plan to

complete the design verification of our AxiLona AXP-100 in the second quarter of 2025, and initiate the clinical trial in the fourth quarter of 2026. Specifically, for our AxiLona EL-100, we will pursue the FDA registration process under the 510(k) pathway. We are working with a CRO on the initial preparation of materials related to 510(k) requirements and have preliminarily identified a potential predicate device that could establish substantial equivalence, which has also undergone a clinical trial. Following this, together with the CRO, we plan to communicate with the FDA on review matters, complete type testing, conduct the requisite clinical trials, prepare comprehensive registration materials, and ultimately submit the 510(k) application.

In European Union where we have obtained the CE marking for our AxiLona EL-100, we will strategically prioritize Central Europe, leveraging its robust ecosystem of early adapters, research funding, and pharmaceutical giants, where we could differentiate through our platform's versatility, rapid test development capabilities, and reduced R&D costs. We will also actively explore the market potential in Eastern Europe by addressing price-sensitive segments with competitively priced, easy-to-operate solutions tailored to local needs. We will first assemble a specialized sales team supported by application scientists, while establishing distribution networks across major areas of the European Union. We will then pursue strategic application development partnerships with leading R&D institutions in main countries while engaging key opinion leaders across various sectors. We plan to launch our products in Europe in renowned academic conferences in late 2025 and 2026, complemented by targeted roadshows to healthcare facilities and pharmaceutical companies.

Further enhance manufacturing capacity for gene sequencing and molecular diagnostic products

We are focused on unlocking the production capacity of our Wuxi manufacturing base, which has been designed to support the manufacture of 1,000 instruments and 100,000 test kit units annually, ensuring it meets the demands of large-scale production. This facility will serve as a cornerstone for scaling our operations and maintaining consistent quality at high volumes.

To align with the anticipated progression of our new product pipeline, we are proactively planning to expand our production capacity. These preparations may include increasing manufacturing space, acquiring advanced equipment, optimizing supply chain management, and ensuring a skilled workforce to meet growing demands.

Furthermore, we are committed to enhancing the automation of our production lines. This includes implementing both fully and semi-automated systems to streamline processes, minimize manual intervention, and improve operational efficiency. By advancing our lean manufacturing capabilities, we aim to reduce production costs, increase output consistency, and respond swiftly to market needs.

OUR PRODUCT AND SERVICE PORTFOLIO

The pipeline chart below summarizes the development status of our product candidates, all of which are in-house developed.

Product	Main Application	Market/Regulatory Authority	Category	Development Stage					Expected/Actual time for Completion of the Current Stage	Expected/ Actual Clinical Trial Start Time	Expected/ Actual Commercialization Approval Time
				Pre-clinical			Clinical Trial[2]	Approval			
				Design	Design Verification	Type Testing[1]					
Devices											
Microarray Analyzer AxiLona EL-100 ★	Nucleic Acid Detection	EU/EU — German Institute for Medical Documentation and Information	A						Q3 2023	/	Q3 2023
		China/Jiangsu MPA[4]	II						Q2 2025	Q3 2024	Q2 2025
		U.S./FDA	II						Q1 2026	Q2 2026	Q3 2027
	Nucleic Acid Detection & Protein Detection[3]	China/Jiangsu MPA[4]	II						Q1 2026	Q4 2026	Q4 2027
		U.S./FDA	II						Q1 2026	Q4 2026	Q4 2028
EL-NGS Gene Sequencer AxiLona AXP-100 ☆	Gene Sequencing	China/NMPA	III						Q4 2025	Q1 2026	Q4 2027
		U.S./FDA	III						Q2 2025	Q4 2026	Q4 2028
EL-NGS Gene Sequencer AxiLona AXP-1000	Gene Sequencing	China/NMPA	III						Q3 2026	Q2 2027	Q2 2029
		U.S./FDA	III						Q3 2026	Q2 2028	Q4 2030
Test Kits											
Test Kit for X-linked Monogenic Disorder[5]	Genetic Disease Detection — Fragile X syndrome	China/NMPA	III						Q4 2025	Q2 2026	Q4 2028
Test Kit for Pathogenic Microorganism[6]	Respiratory Multiplex testing	China/NMPA	III						Q2 2026	Q4 2026	Q2 2029
	Meningitis	China/NMPA	III						Q1 2026	Q3 2026	Q3 2028

★ Core Product ☆ Key Product

Abbreviations: Q1 means the first quarter; Q2 means the second quarter; Q3 means the third quarter; Q4 means the fourth quarter

Notes:

(1) For the FDA registration in the U.S., type testing refers to safety and performance testing.

(2) In the EU, Nucleic Acid Detection is regulated under the In Vitro Diagnostic Regulation (IVDR). Under the IVDR, Nucleic Acid Detection devices classified as Class A are exempt from the requirement for clinical trials.

(3) Although AxiLona EL-100 for nucleic acid detection and AxiLona EL-100 for both nucleic acid and protein detection differ in detection targets, reagent kits and software modules, they share the same hardware configuration and will be regulated as one product by Jiangsu MPA.

(4) According to the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》), as a Class II medical device, EL-100 is regulated by the Jiangsu MPA.

(5) Designed for use in conjunction with AxiLona AXP-100.

(6) Designed for use in conjunction with AxiLona EL-100.

Our electrochemical long-read next-generation sequencing (EL-NGS) platform underpins both of our products and spans four key areas: integrated circuit chips, synthetic biology and chemical engineering, electrochemistry and microfluidics, and artificial intelligence.

Our integrated circuit chip technology enables high-throughput, low-cost, and high-precision sequencing, providing essential capabilities for both products, such as multi-target detection and nanopore sequencing. Our synthetic biology and chemical engineering platform enhances the quality of biomarkers and improves enzyme performance, ensuring accurate and reliable results. The integration of electrochemical and microfluidic technologies makes our products more cost-effective, portable, and efficient. Additionally, AI algorithms optimize the accuracy of sequencing and bioinformatics analysis, allowing for continuous improvement in both diagnostic and sequencing applications. See "— Research and Development — Our Technology Platform" for further information.

We provide comprehensive gene sequencing or molecular diagnostics solutions to our customers, including packages that integrate instrument, test kits, and other essential consumables. This end-to-end approach ensures clients receive a fully optimized testing system rather than isolated components.

AxiLona EL-100 — Our Core Product

We are developing AxiLona EL-100, a molecular diagnostic product based on electrochemical biochip technology. AxiLona EL-100 is one of the few molecular diagnostic product in China capable of performing electrochemistry-based, multi-target, rapid, low-cost, and integrated detection of biomolecules. It delivers improved performance over conventional PCR systems, featuring as multiplex target detection through 54 addressable electrodes that enable simultaneous analysis (up to 54 targets subject to our applications), high sensitivity (with a detection limit as low as 100 copies/ml), a rapid testing cycle (<2 hours), and exceptional user-friendly flexibility. AxiLona EL-100 has demonstrated a favorable safety profile and was found to meet the applicable national and industry safety standards, including GB 4793.1-2007, GB 4793.9-2013 and YY 0648-2008, as established in the type testing report. Type testing is a mandatory step in the medical device registration process in China. The type testing shall be conducted in accordance with the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》), which require that medical devices undergo testing against applicable product technical requirements prior to clinical trial initiation or registration application. These features make it well-suited for scientific research supported by RUO test kits, and for clinical applications supported by developing test kits with regulatory approval or through other pathways, distinguishing it from competing molecular diagnostic products. According to the device registration specification approved by Jiangsu MPA, our EL-100 provides qualitative analysis of current signals from nucleic acid microarray chips for nucleic acid-based medical testing applications and does not perform absolute quantification of nucleic acid samples.

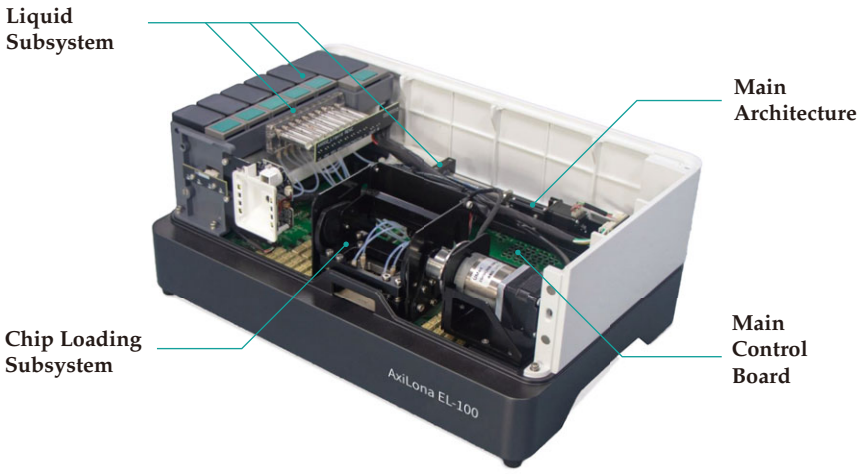
Appearance of AxiLona EL-100

AxiLona EL-100 was admitted into the Special Registration Procedures for Innovative Class II Medical Devices (commonly known as Green Path) by the Jiangsu MPA in June 2024. We completed its clinical trial in March 2025, and have received the Class II medical device registration certificate for AxiLona EL-100 from Jiangsu MPA in April 2025. This registration approves microarray analyzer for the qualitative analysis of signals generated by nucleic acid microarray chips in support of nucleic acid-based medical testing applications, and is not intended for absolute quantification of nucleic acid samples. These microarray chips are components of test kits, and AxiLona EL-100 must be used in conjunction with compatible test kits for any clinical or research use only applications. We also received the CE marking for AxiLona EL-100 in July 2023. The targeted indication for the original version of AxiLona EL-100 is nucleic acid detection alone, and we plan to develop an upgraded version to cover both nucleic acid detection and protein detection.

Test kits are designed to be used in conjunction with AxiLona EL-100 for both clinical applications and RUO purposes. The microarray analyzer works with compatible test kits containing a microarray chip to collect and analyze electrical signals from the nucleic acid microarray chip. This allows for qualitative detection in nucleic acid-based testing, and it, as a versatile platform, can be applied to scientific research supported by RUO test kits, to clinical applications supported by developing test kits with regulatory approval or through other pathways. We are actively enhancing its capabilities with a new suite of specialized test kits. In clinical settings, our existing and upcoming kits will enable AxiLona EL-100 to detect multiplex respiratory pathogens (five targets) and multiplex meningitis pathogens (seven targets). For life science research, AxiLona EL-100 supports assays such as respiratory syncytial virus (RSV), multiplex respiratory detection panels (including 3-plex and 16-plex options) and single nucleotide polymorphism (SNP) detection for high-altitude adaptation studies. We are also pursuing collaborative opportunities with third parties, including end-users of the AxiLona EL-100, to develop innovative test kits for targeted indications. There is no difference in the regulatory approval pathways between our self-developed test kits and those developed by third parties.

Product Components and Operation Procedure

AxiLona EL-100 is composed of several key components: a main framework (housing), a main control board (electronic circuitry system), a chip loading subsystem (including mechanical movement parts and current signal acquisition module), a liquid flow subsystem (containing the reagent storage system and liquid circulation system), adapters, and software.



Key Components of AxiLona EL-100

AxiLona EL-100 uses a motor-driven mechanism to automatically load and eject disposable microarray chips, ensuring smooth electrical connection between the chip and the device. The user operates the system via a computer with a mouse and keyboard. Data is exchanged between the computer and the device through a USB cable, allowing the computer to read and analyze the sample electrical signals collected by the device.

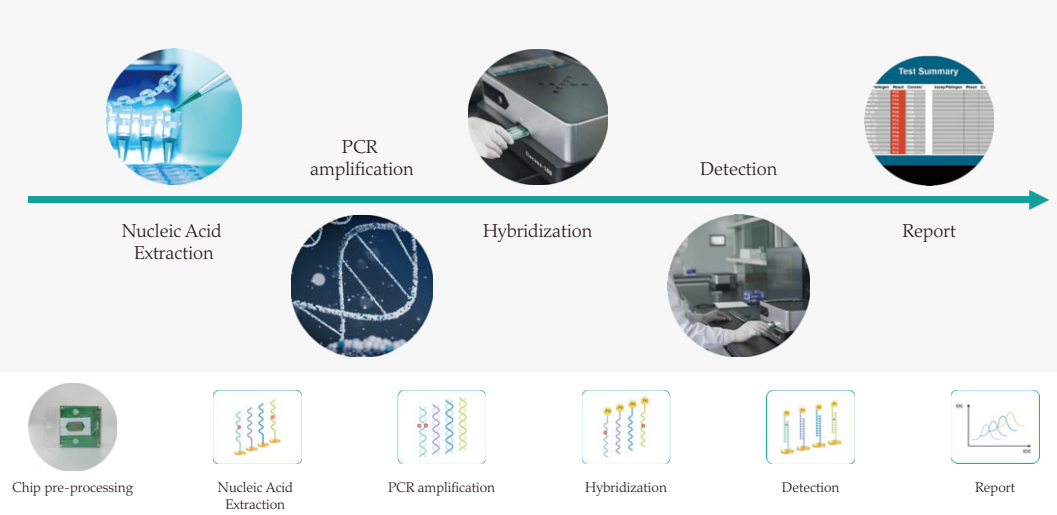
The workflow of AxiLona EL-100 is as follows:

- ***Chip fabrication.*** Multiple oligonucleotide probes are immobilized on the chip using specialized techniques. The design of the chip ensures that the probes are arranged in a precise spatial pattern, facilitating accurate discrimination of targets during the hybridization process.

- ***Sample preparation.*** The workflow begins with nucleic acid extraction from biological samples such as blood or nasal swabs. Once the nucleic acid is extracted, multiplex PCR amplification is performed, serving as library preparation step to produce detectable targets.

- ***Hybridization.*** The electrochemical labeled targets together with controls then are mixed and applied to the fabricated chip, which is followed by washing steps to remove the non-specific interactions.

- ***Signal detection and analysis.*** After short hybridization, the chip is loaded into AxiLona EL-100. When voltage is applied to the chip, redox reactions generate distinctive electrical signals. The signals are then processed by specialized software to produce test report accordingly.



Workflow of AxiLona EL-100

AxiLona EL-100 can scan barcodes on the microarray chip and sample cards, or users can manually input the chip and sample card information. During testing, the device displays its operational status and data. After testing, AxiLona EL-100 automatically generates and stores results. The product allows for sorting, filtering, exporting, and reviewing of results. Each test takes approximately three minutes to complete.

Product Features and Technical Advantages

As a next-generation molecular diagnostic platform based on microarray and electrochemical signal sensors, the AxiLona EL-100 addresses the limitations of existing fluorescence PCR products, such as the limited number of detectable targets, and the high cost and lengthy cycle time of mNGS (massively parallel sequencing) testing. It offers the following significant advantages:

- ***Multiplex detection.*** AxiLona EL-100 can detect up to 54 nucleic acid targets simultaneously, making it highly versatile for various diagnostic needs. This multi-target detection capability significantly enhances its diagnostic efficiency compared to traditional methods, which typically focus on only four to six targets at a time. By enabling the detection of multiple biomarkers in a single test, it improves throughput and offers comprehensive analysis in a shorter period.

- ***Cost-effectiveness.*** The use of electrochemical sensors in AxiLona EL-100 significantly reduces the overall cost of testing. Other multi-target molecular diagnostics, especially mNGS and tNGS, can be expensive, due to the need for complex equipment and test kits. In contrast, the electrochemical approach used in AxiLona EL-100 lowers costs by 1/2-1/3, making it more affordable for both clinical and research applications.

- ***High sensitivity.*** AxiLona EL-100 also stands out for its high sensitivity, with a detection limit as low as 100 copies/ml, compared with the detection limits of 300 to 500 copies/ml for instruments currently registered in China. Additionally, whereas most routine PCR platforms have limits of detection in the 100–1,000 copies/mL range, the EL-100 can detect as few as 100 copies/mL, underscoring its superior analytical sensitivity. Such characteristic is crucial for accurate and timely diagnoses and detection.

- ***Rapid testing cycle.*** AxiLona EL-100 delivers results in under two hours, which is much faster than many conventional molecular diagnostic methods. This rapid turnaround time is crucial in various clinical and research applications.

- ***User-friendly design***. The device is designed to facilitate ease of use. After sample addition and incubation, the process is simplified to just loading the chip and pressing a single button to initiate the test.

- ***Compact and portable size.*** Weighing only 6.15kg and designed with a compact form factor, AxiLona EL-100 is highly portable. Unlike large-scale instruments designed exclusively for centralized, high-throughput environments, EL-100 features a compact and lightweight design. This makes it suitable not only for high-volume laboratories but also for decentralized testing scenarios, such as smaller hospitals or regional clinics where space is a key consideration.

Market Opportunity and Competition

Among the existing non-sequencing molecular testing products utilizing multiplex PCR-microarray technologies, a majority of them are based on fluorescence microarray detection and few opine on electrochemical microarray detection which offers higher sensitivity and specificity, greater multiplexing capacity, lower costs, simpler and more compact instrumentation, and a streamlined workflow compared to fluorescence-based systems. According to CIC, the global electrochemical multiplex PCR-microarray testing market increased from US$93.3 million in 2018 to US$397.6 million in 2024, and is projected to reach US$1,027.8 million in 2033 with a CAGR of 11.1%. China's electrochemical multiplex PCR-microarray testing market increased from US$1.3 million in 2018 to US$2.2 million in 2024, and is projected to reach US$56.4 million in 2033 with a CAGR of 43.6%. The U.S. electrochemical multiplex PCR-microarray testing market increased from US$23.3 million in 2018 to US$105.5 million in 2024, and is projected to reach US$292.6 million in 2033 with a CAGR of 8.2%. The EU electrochemical multiplex PCR-microarray testing market increased from US$12.7 million in 2018 to US$220.9 million in 2024, and is projected to reach US$448.5 million in 2033 with a CAGR of 12.0%.

As of the Latest Practicable Date, there were an aggregate of 80 multiplex PCR-microarray testing instruments developed by 58 companies had been approved by the NMPA or its local counterparts, of which only two were electrochemical platforms, including our Core Product AxiLona EL-100. In 2024, the top five players in China's non-sequencing molecular testing market collectively held over 50% of the market share by revenue, with the single largest player accounting for 13.2%. In contrast, the electrochemical multiplex PCR-microarray testing segment was highly concentrated, with

the only two approved instruments capturing the entire market share in China for the same year. The chart below illustrates the competitive landscape of China's multiplex PCR microarray analyzer market.

Analysis of China's competitive landscape of multiplex PCR microarray analyzer market

Indicator	Multiplex PCR + Fluorescence Microarray Detection	Multiplex PCR + Electrochemical Microarray Detection
Sensitivity	• ≥200 Copies/mL	• Can be as low as 100 Copies/mL
Specificity[1]	• ~97% (only specific primers for amplification 90%~95%)	• >99.9% (The combination of specific primers for amplification and highly specific probes for hybridization significantly improves specificity)
Sample Throughput per Unit Time	• Relatively low	• High
Instrument Cost	• High, complex optical components lead to high instrument cost	Low, no complex optical components, 1/3-1/2 the cost of a fluorescent quantitative PCR instrument
Reagent Cost	• Relatively high (signal detection requires multiple fluorescent-labeled probes like TaqMan probes, increasing production cost)	• Low, about 1/2 the cost of fluorescent detection reagents (only one electrochemical group is needed per signal detection; thus only one type of label is needed, resulting in lower production cost)
Number of NMPA approval product	• 78	• 2
Key Players	• CapitalBio • Affymetrix • Agilent	• Axbio • Daan Gene

Source: NMPA, public information, literature review, CIC

Our AxiLona EL-100 was strategically developed to address substantial market opportunities. While not universally applicable to every end-user category, the platform demonstrates extensive market reach and customer base potential. Built on an innovative technology platform, the AxiLona EL-100 delivers cost-effective, high-multiplex detection capabilities that are particularly well-suited for pathogen detection and genetic disease screening applications. Notably, high-multiplex pathogen detection represents a significant market opportunity with diverse application scenarios.

Following receipt of the Class II medical device registration certificate for the AxiLona EL-100 microarray analyzer, we are actively developing various test kits by ourselves and pursuing collaborations with downstream partners across various sectors to co-develop specialized test kits, systematically expanding both clinical and research applications. Our commercialization strategy encompasses multiple pathways, including pursuing NMPA-approved in vitro diagnostic (IVD) kits, developing laboratory-developed tests (LDTs) tailored to specific clinical requirements, and offering RUO test kits. This flexible approach enables us to respond dynamically to end-user demands while capturing broader market opportunities.

Summary of Clinical Trial Results

Trial design

We initiated a clinical trial to evaluate the clinical safety and effectiveness of the AxiLona EL-100 in August 2024. This clinical trial is designed to evaluate as a proxy for general functionality rather than for full-panel validation.

The clinical trial design for AxiLona EL-100 was formulated to validate the efficacy and safety of AxiLona EL-100 as a microarray analyzer for nucleic acid detection applications. The clinical trial design is scientifically robust, primarily aimed at demonstrating that AxiLona EL-100 possesses functional capabilities and competency in nucleic acid detection with established safety profiles. The selection of control system was

intended to demonstrate that AxiLona EL-100 exhibits equivalent nucleic acid detection capabilities compared to the control systems, rather than to prove superior or equivalent performance to other products utilizing the same electrochemical technology. Considering that other similar products using electrochemical technology have not been widely commercialized and are not considered standard in current clinical practice, comparisons with such products in clinical trials are seen as lacking clinical and scientific relevance. In contrast, the control systems selected for our clinical trials are established standards in current clinical practice, making them more appropriate for clinical trial design.

In this trial, the AxiLona EL-100 was used in conjunction with a self-developed nucleic acid detection kit for respiratory syncytial virus (RSV) as the test system and a commercially available real-time fluorescence quantitative PCR instrument and respiratory pathogen nucleic acid detection kit were used as the control system for RSV detection on the same swab sample. The respiratory pathogen nucleic acid detection kit used by the control system is a third-party commercially available test kit developed and manufactured by a molecular diagnostics company based in China. The control kit is an approved product, and is designed for the qualitative detection of six common respiratory pathogens using PCR fluorescence probe technology. AxiLona EL-100 functions as a nucleic acid detection platform that operates together with compatible test kits and supporting software. The test kits capture and hybridize specific target nucleic acids, the analyzer controls the fluidic and electrical processes to collect and digitize detection signals, and the software manages instrument operation, data processing, and result interpretation. The analytical performance of AxiLona EL-100 reflects the integrated operation of these three components, each contributing distinct but complementary functions to achieve accurate and reliable detection. The trial evaluated the consistency of the detection results of test system and control system to demonstrate nucleic acid detection capability and efficacy, including positive agreement rate, negative agreement rate, overall agreement rate, and Kappa value. Additionally, during the use of the instrument, the trial assessed the AxiLona EL-100's functionality, stability, user-friendliness, and safety.

The trial enrolled patients with suspected respiratory infections, exhibiting symptoms such as cough, nasal congestion, sore throat, fever, headache, and muscle aches, and used throat swab samples for testing. Eligible participants were of any age or sex, provided throat swab samples, and were able to understand the study procedures and voluntarily participate by signing informed consent. The participants had an average age of 33.9 years, with ages ranging from 0 year (infants under six months were recorded as 0 year) to 102 years. Of these participants, 131 were male (53.7%) and 113 were female (46.3%), with no special population groups included. Participants were excluded if adequate samples could not be collected, if the sample quantity was insufficient or deemed unsuitable due to improper collection or storage, or if clinical or demographic information such as sex, age, or diagnostic data was incomplete. One sample was excluded during the clinical trial because the control test tube was deformed during the amplification process, rendering the sample untestable. This exclusion met the pre-defined criteria in the clinical protocol for removing samples that could not be tested due to collection, extraction, storage, or operational errors.

Trial status

Our AxiLona EL-100 was admitted into the Special Registration Procedures for Innovative Class II Medical Devices (commonly known as Green Path) by the Jiangsu MPA in June 2024. We completed its clinical trial in March 2025, and have received the Class II medical device registration certificate for AxiLona EL-100 from Jiangsu MPA in April 2025. This registration approves our microarray analyzer for the qualitative analysis of signals generated by nucleic acid microarray chips in support of nucleic acid-based medical testing applications, and is not intended for absolute quantification of nucleic acid samples.

Trial results

Based on our inclusion and exclusion criteria, 244 evaluable subjects were enrolled in this clinical trial. Though our AxiLona EL-100 and the control system operate under different technical principles, the consistency rate for the positive samples between the test system (AxiLona EL-100) and the control system was 100.00%, the consistency rate for the negative samples between the test system (AxiLona EL-100) and the control system was 100.00%, and the overall consistency rate was 100.00%. The Kappa value was 1.0000 (>0.75), indicating excellent detection consistency between the test system and the control system.

As to functionality, in this clinical trial, each positive and negative quality control sample yielded qualified results, with no instances of quality control failure. Also, during operation, the device correctly identified microarray chips, displayed working status, reported and stored detection results, and functioned normally, demonstrating high stability. In the stability evaluation, which examined operating status, occurrence of malfunctions, and the ability to sustain continuous work, the microarray analyzer maintained continuous operation without abnormal operations. As to convenience of use, in the user convenience evaluation form, which assessed 10 usability criteria including the user-friendliness of the interface and the simplicity of the detection workflow, the microarray analyzer received consistently high ratings, with the average user rating reaching 98 (out of 100). Furthermore, we conducted safety evaluation to cover 12 items such as risks of electric leakage, short circuit, pinching, collision, cuts, burns, or liquid leakage. No safety-related events occurred.

We believe that the clinical trial results are complete and sufficient, and include all material data submitted to and considered by the Jiangsu MPA as part of the registration review process. As of the Latest Practicable Date, there are no additional positive or negative results that have not been disclosed. The clinical results were determined to have met all relevant regulatory evaluation criteria, and were considered adequate to support the registration of AxiLona EL-100 as a Class II medical device, on the basis that:

- The high sensitivity of AxiLona EL-100 was supported by our pre-clinical validation studies, in which weak-positive, medium-positive, and strong-positive samples were tested. The results showed that the electrical signal values detected by AxiLona EL-100 varied proportionally with the concentration levels of the samples, accurately distinguishing between

positive and negative results, thereby confirming the instrument's high analytical sensitivity. The accurate detection of weak-positive samples particularly demonstrates the high sensitivity of the EL-100 system, thereby confirming the instrument's robust analytical sensitivity. Although the clinical trial focused on a single-pathogen (RSV) for regulatory purposes, the study also involved the simultaneous detection of an internal reference gene (housekeeping gene) within the same assay, demonstrating the system's capacity for concurrent detection of multiple targets.

- AxiLona EL-100's technical design, which features 54 independent and addressable electrodes, each capable of detecting a single target, has been validated at the engineering and pre-clinical levels to support multiplex detection of up to 54 distinct targets within a single test run.

Taken together, the design verification, pre-clinical validation, and clinical evaluation collectively demonstrate the safety, stability, and analytical performance of AxiLona EL-100. Nothing has come to the attention of the Joint Sponsors that would cause them to disagree with the Company's view on the clinical trial results as mentioned above.

Further Development Plan

Our further development plan and regulatory pathways for AxiLona EL-100 in nucleic acid detection in the targeted jurisdictions are as follows:

In China, we have completed clinical trials for nucleic acid detection and received Class II medical device approval from the Jiangsu MPA in April 2025. The registration certificate authorizes EL-100 for qualitative analysis of signals generated by nucleic acid microarray chips, supporting nucleic acid-based medical testing applications. Following approval, we commenced commercialization activities, signed distribution agreements with multiple distributors, and initiated customer engagement programs.

We plan to expand the clinical applications of AxiLona EL-100 by adding protein detection functionality to enable both nucleic acid detection and protein detection and address the huge market potential of protein testing. To achieve this, we plan to upgrade the existing device by further developing surface modification and different capture probes, thereby delivering rapid, high-sensitivity protein detection with minimal user input. From a technical and design perspective, AxiLona EL-100 requires no hardware modifications to enable protein detection — only algorithm and software adaptations. Algorithm adaptation involves adjusting digital filtering parameters, signal threshold types, and detection settings, with the software being able to display results based on these adjustments. The matching cartridge similarly requires no hardware modifications and needs only to be paired with protein detection kits. The primary difference between protein and nucleic acid detection reagents lies in capture probe composition: nucleic acid detection utilizes modified oligonucleotides, while protein detection employs specific antibodies. Regarding workflow, protein detection does not require the amplification step. Following pre-processing (such as centrifugation or dilution), samples are directly introduced into the detection cartridge for incubation with the capture probe and subsequent signal detection. The system then processes the detected signal to generate a diagnostic report. The Company plans to complete the EL-100 protein detection system

design in the first quarter of 2026, and then initiate the design verification and other preclinical studies. Subsequently, specific test kit development will be selected based on market conditions and device performance. Several potential directions are under consideration: (i) detecting protein biomarkers for early screening and diagnosis of Alzheimer's disease, (ii) identifying allergens, and (iii) analyzing immune factors to aid in diagnosing sepsis, certain infections, and autoimmune disorders.

In the United States, we plan to finish the type testing of our AxiLona EL-100 in nucleic acid detection in the first quarter of 2026 and initiate clinical trial in the second quarter of 2026. We also plan to finish the design of the upgraded version of AxiLona EL-100 that covers both nucleic acid detection and protein detection in the first quarter of 2026, and initiate clinical trial in the fourth quarter of 2026. We will pursue the FDA registration process under the 510(k) pathway. We have identified and held discussions with several CROs regarding potential registration plans, and expect to proceed with formal engagement in the near term. Following this, together with the CRO, we plan to communicate with the FDA on review matters, complete type testing, conduct the requisite clinical trials, prepare comprehensive registration materials, and ultimately submit the 510(k) application. The 510(k) pathway is a premarketing submission to the FDA demonstrating that a device is safe and effective through substantial equivalence to a legally marketed device (the predicate device). While recently cleared devices are commonly used as predicates, any legally marketed U.S. device may serve this purpose. According to FDA guidance, adding a new indication typically requires a new 510(k) submission to obtain clearance for the updated device incorporating both the previously cleared indication and the new one — in our case, both nucleic acid and protein detection functionalities.

In the European Union where we have obtained the CE marking for our AxiLona EL-100, we will strategically prioritize Central Europe, leveraging its robust ecosystem of early adapters, research funding, and pharmaceutical giants, where we could differentiate through our platform's versatility, rapid test development capabilities, and reduced R&D costs. We will also actively explore the market potential in Eastern Europe by addressing price-sensitive segments with competitively priced, easy-to-operate solutions tailored to local needs. We will first assemble a specialized sales team supported by application scientists, while establishing distribution networks across major areas of the European Union. We will then pursue strategic application development partnerships with leading R&D institutions in main countries while engaging key opinion leaders across various sectors. We plan to launch our products in Europe in renowned academic conferences in late 2025 and 2026, complemented by targeted roadshows to healthcare facilities and pharmaceutical companies.

For further details on the addressable market and competitive landscape in China's market, please see "Industry Overview — Non-Sequencing Molecular Testing Market — Non-sequencing molecular testing market size." For further details on the regulatory framework in China, please see "Regulatory Overview — Relevant Laws and Regulations in the PRC — Regulation of Medical Devices."

Our further development plan and regulatory pathways for AxiLona EL-100 in nucleic acid detection & protein detection in the targeted jurisdictions are as follows:

In China, according to consultations with Jiangsu MPA, the addition of protein detection functionality constitutes a registration variation and will be regulated under the same Class II certificate. The upgraded version of EL-100 will not be regarded as a distinct microarray analyzer. We plan to initiate clinical trials for the upgraded EL-100 in fourth quarter of 2026.

In the United States, we plan to pursue FDA registration under the 510(k) pathway for the combined nucleic acid and protein detection functionality. We expect to complete design in Q1 2026 and initiate clinical trials in Q4 2026. The product classification is expected to be Class II.

For further details on the addressable market and competitive landscape in the United States, please see "Industry Overview — Non-Sequencing Molecular Testing Market — Non-sequencing molecular testing market size" and "Industry Overview — Protein Testing Market Protein testing market size." For further details on the regulatory framework in the United States, please see "Regulatory Overview — Relevant Laws and Regulations in the United States."

Commercialization Plan

To support market acceptance and user adoption of the AxiLona EL-100, we have adopted a multi-pronged commercialization strategy, including: (i) expanding our national distributor network to cover hospitals, research institutions and government laboratories; (ii) co-marketing with distributors through academic seminars, product demonstrations and trial programs; and (iii) partnering with key opinion leaders to promote clinical recognition. We have entered into collaborations with institutions such as Center for Frontier Medicine at West China Hospital of Sichuan University, Shenzhen CDC and Kunming University of Science and Technology, and are in early-stage discussions with Brown University to explore potential opportunities in the U.S. These collaborations typically involve trial use of AxiLona EL-100, validation of its performance on existing sample sets, and exploration of customized or co-developed test kits, which may proceed under either the LDT framework in hospitals or as RUO projects in research institutions.

Our sales model is structured around both direct and distributor-led channels. For hospitals and research institutions, we use a direct sales approach supported by an internal sales team. For broader coverage, we rely on experienced distributors selected based on regional capabilities and compliance readiness. Following the approval of AxiLona EL-100 as a Class II medical device in April 2025, we commenced sales and marketing activities in China. As of the Latest Practicable Date, we had sold two units of AxiLona EL-100 to a distributor.

Our commercialization strategy is based on a dual-revenue model involving (i) initial device sales and (ii) recurring sales of test kits. Each AxiLona EL-100 device serves as a base for the recurring use of compatible test kits, which are either developed in-house or in collaboration with third parties. Clinical end-users typically procure our test kits along with the instrument, while KOL customers may also develop their own. This integration between hardware and consumables strengthens customer stickiness and supports a scalable and sustainable revenue model.

While AxiLona EL-100 requires test kits and specialized software to generate test reports, the software is self-developed and registered under software copyright. It serves as the control interface for EL-100, enabling device operation, signal acquisition, data analysis, user management, and maintenance. The software is bundled with the device and does not require separate licensing, ensuring seamless deployment and user experience.

Despite the technical advantages of EL-100, including multiplex target detection, lower costs, and accelerated testing cycles, the hospital procurement and validation process is complex and involves multiple steps. This multi-step process typically involves: internal budget approvals; equipment trial and performance validation; tendering and procurement procedures; compatibility assessment with test kits; and regulatory and institutional qualification reviews. In addition, as EL-100 represents a novel technology, certain end-users may require market education and demonstration to overcome inertia from existing procurement practices and brand preferences.

We are currently developing a pipeline of clinical test kits for AxiLona EL-100, including panels for respiratory infections and meningitis, which are in the design verification stage and expected to be launched by 2029. In parallel, we are collaborating with third parties to develop RUO test kits targeting additional applications such as pathogen surveillance, SNP genotyping, gut microbiome analysis and genetic disorders.

Although our proprietary clinical test kits are not expected to be commercialized until 2028-2029, we intend to support installed EL-100 devices through collaborations with third-party developers. While there are no fully off-the-shelf third-party kits compatible with EL-100 due to its electrochemical detection mechanism, conventional PCR cartridges can be adapted with technical support. We have established a primer and probe design platform and a synthetic biology platform to assist third-party developers in customizing reagents for EL-100. RUO test kits are also expected to contribute to EL-100 sales, particularly in research institutions and hospitals with LDT qualifications. These kits enable EL-100 to be used in basic research, translational studies, and exploratory clinical collaborations, thereby cultivating a user base and expanding application scenarios.

The average break-even period for comparable diagnostic instruments in the industry is typically 8 to 10 years, based on research on leading domestic listed companies such as Airdoc Technology Inc., Sansure Biotech Inc., and Assure Tech (Hangzhou) Co., Ltd. This extended timeline reflects substantial upfront R&D investment, lengthy regulatory approval processes, and the time required to build recurring reagent revenue streams.

Material Communications with Competent Authorities

In February 2024, we applied to the NMPA Medical Device Standard Management Center for classification of AxiLona EL-100 and received a notice confirming its classification as a Class II medical device in April 2024.

In May 2024, we submitted an application for the Special Registration Procedures for Innovative Class II Medical Devices (commonly known as Green Path) for AxiLona EL-100 to the Jiangsu MPA and was admitted into Green Path in June 2024.

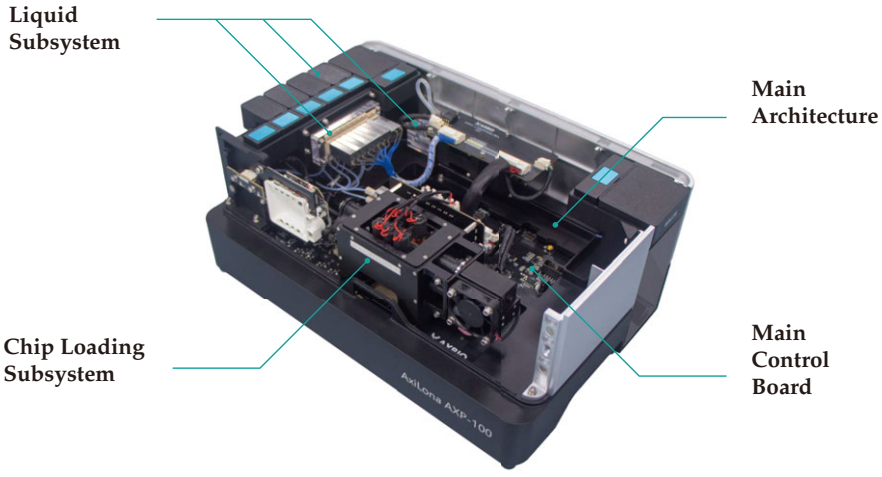
In April 2025, we received the Class II medical device registration certificate for AxiLona EL-100 from Jiangsu MPA. This registration approves microarray analyzer for the qualitative analysis of signals generated by nucleic acid microarray chips in support of nucleic acid-based medical testing applications, and is not intended for absolute quantification of nucleic acid samples. According to our consultations conducted by our PRC Legal advisor with Jiangsu MPA in April 2025, our planned protein detection expansion will be regarded as an upgraded version of AxiLona EL-100 and will be regulated under the same certificate with AxiLona EL-100.

WE MAY NOT BE ABLE TO ULTIMATELY UPGRADE AND MARKET AXILONA EL-100 SUCCESSFULLY.

AxiLona AXP-100

AxiLona AXP-100 EL-NGS gene sequencer is the world's first EL-NGS product, according to CIC. It achieves an optimal balance across four critical metrics: accuracy, read length, cost, and speed. We launched the product prototype of AxiLona AXP-100 in 2021, launched it for research use in 2023 and realized end-user installation in 2024. In scientific research, the AxiLona AXP-100 can be used for studies on structural variations, analysis of tandem repeat regions, as well as research into single-gene diseases. We also plan to actively pursue the clinical application of AxiLona AXP-100. The clinical applications of the AxiLona AXP-100 include cancer diagnosis, infectious disease and infection diagnosis, as well as reproductive defect diagnosis. We expect to complete the type testing for AxiLona AXP-100 in the second half of 2025 in China and subsequently initiate a clinical trial for AxiLona AXP-100, after which we will pursue regulatory registration based on the trial outcomes. We plan to develop universal test kits for AxiLona AXP-100, and test kits with specialized application across domains of genetic disorders, microbiology, and oncology.

Appearance of AxiLona AXP-100

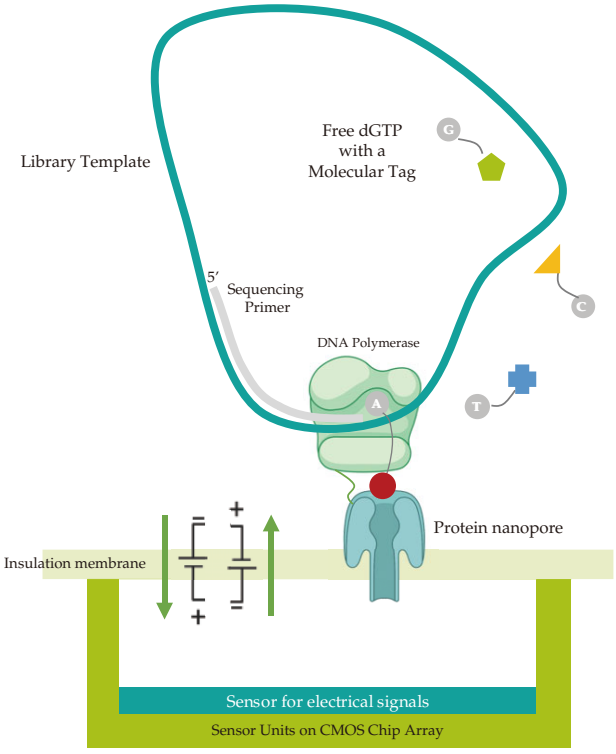


Key Components of AxiLona AXP-100

Product Description and Operation Procedure

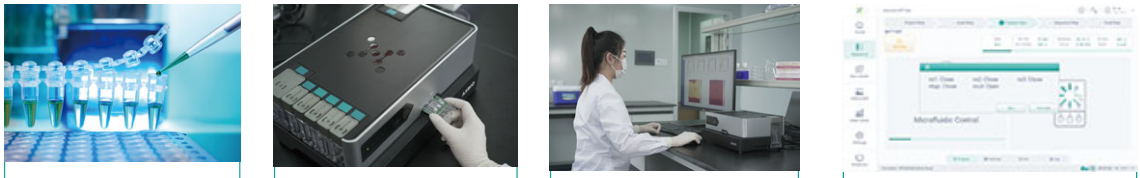
In the AxiLona AXP-100, individual nucleic acid molecules, which are labeled with molecular tags, are attached to polymerases captured by nanopores. During the primer extension process, nucleotides with corresponding tagged molecules pass through the nanopores sequentially, generating distinct electrical signals. These signals are used by the device to characterize the base sequence of the nucleic acid, enabling high-accuracy sequencing.

The diagram below illustrates the technical principle of EL-NGS, where synthesis and sequencing occur simultaneously, in the AxiLona AXP-100.



EL-NGS of AxiLona AXP-100

The diagram below demonstrates the workflow of AxiLona AXP-100.



Workflow of AxiLona AXP-100

Product Features and Technical Advantages

Our EL-NGS gene sequencer AxiLona AXP-100 offers several key advantages that make it a highly efficient and reliable tool for gene sequencing and molecular diagnostics:

- ***Longer read lengths.*** By introducing the groundbreaking EL-NGS using proprietary polymerases and molecular tags, AxiLona AXP-100 enables simultaneous synthesis and sequencing. This technology allows for single-molecule cyclic sequencing with repetitive consensus analysis, ensuring long reads, high precision, and real-time sequencing and data output.

- ***High accuracy.*** AxiLona AXP-100 integrates AI algorithms for base calling and cyclic consensus sequence correction, enhancing the efficiency and accuracy of sequencing. With an accuracy rate greater than 99%, the AxiLona AXP-100 ensures highly reliable and precise results.

- ***Fast sequencing.*** The AxiLona AXP-100 is capable of generating data at a high rate, producing up to one million reads instantly. This enables real-time sequencing with a turnaround time of less than 4 hours, significantly reducing the time required to obtain results compared to other sequencing methods.

- ***Compact and portable.*** Despite its distinct capabilities, the AxiLona AXP-100 is designed to be small and lightweight. With a volume of just 0.013m^3 and a weight of around 6.85kg, it is highly portable, making it suitable for use in various settings.

- ***Flexible and on-demand operation.*** One of the advantages of the AxiLona AXP-100 is its flexibility in sample processing. Samples can be tested as they arrive, without the need to batch samples together. This on-demand testing capability ensures quick and efficient sample analysis without delays.

- ***Cost-effective.*** The cost per Gigabases of data generated by the AxiLona AXP-100 is significantly lower than that of traditional NGS technologies. This makes it a more affordable option for high-throughput sequencing, providing great value for both clinical and research applications.

We understand AxiLona EL-100, our Core Product, and AxiLona AXP-100 will not be regulated as a single product. These medical devices exhibit significant distinctions in their biochemical technologies, functionalities, and applications, following different development pathways. They are fundamentally two distinct medical devices rather than functional extensions of the same medical device. Specifically, the two devices employ different biochemical methodologies. AxiLona EL-100 utilizes hybridization technology to detect nucleic acid, where single-stranded nucleic acid probes hybridize with target nucleic acids in the sample through complementary base pairing to form stable double-stranded structures, which are then detected via electrochemical signals. In contrast, AxiLona AXP-100 employs sequencing technology to determine analyze structure, function, and mutations. It bounds individual nucleic acid molecules labeled

with molecular tags to polymerase captured within nanopores. Nucleotides with corresponding molecular tags then sequentially pass through the nanopore, generating unique electrical signals for high-precision sequencing.

Market Opportunity and Competition

Recent advances in both global and China's gene sequencing markets have been largely driven by the adoption of next-generation sequencing technologies. As demand for long-read, more cost-effective, and more comprehensive genomic analysis grows, high-throughput sequencing platforms have emerged as the backbone of this progress, enabling the parallel sequencing of millions of DNA molecules and significantly expanding the scale and efficiency of genomics research and clinical applications.

The high-throughput gene sequencing segment has experienced robust growth in recent years and is projected to accelerate further, positioning itself as one of the most dynamic drivers within the broader gene sequencing landscape. The global high-throughput gene sequencing market grew from US$4.7 billion in 2018 to US$7.1 billion in 2024, reflecting a CAGR of 7.1%, which is expected to reach US$21.9 billion in 2033, with a CAGR of 13.2%. China's high-throughput gene sequencing market increased from US$0.9 billion in 2018 to US$1.3 billion in 2024, reflecting a CAGR of 6.0%, which is expected to reach US$5.3 billion in 2033, with a CAGR of 17.4%.

The global high-throughput gene sequencing instrument and consumables market is highly concentrated and dominated by a few multinational biotechnology companies. In 2024, the top five players accounted for an aggregate market share of 94.9%, with Illumina alone capturing a significant share of 71.8%, in terms of their respective revenue in the same year. The table below sets forth the top five players in the global high-throughput gene sequencing instrument and consumables market and their respective market shares by revenue in 2024.

Company	Revenue (billion USD)	Market share (%)
Illumina	3.5	71.8%
Thermo Fisher Scientific	0.4	8.3%
MGI	0.3	7.1%
Oxford Nanopore Technologies	0.2	4.6%
Pacific Biosciences	0.1	3.0%

Notes:

(i) Market share represents each company's revenue from gene sequencing instruments, compatible consumables, and after-sales maintenance service in the global high-throughput gene sequencing instrument and consumables market.

Source: Annual reports of listed companies, JPM conference, expert interviews, CIC

The competitive landscape of China's high-throughput gene sequencing instrument and consumables market shares the same pattern as the global market, with similar dominant players and level of market concentration. In 2024, the top five players collectively secured 95.8% of the market share by revenue in the same year. While Illumina leads both globally and in China, the market share distribution in China is more balanced than that globally due to MGI's significant presence as a prominent local player. As of the Latest Practicable Date, 38 high-throughput gene sequencing instruments by 23 players had been approved by the NMPA or its local counterparts. The table below sets forth the top five players in China's high-throughput gene sequencing instrument market and their respective market shares by revenue in 2024.

Company	Revenue (billion RMB)	Market share (%)
Illumina	2.0	47.0%
MGI	1.7	39.0%
Thermo Fisher Scientific	0.2	4.3%
Oxford Nanopore Technologies	0.1	3.2%
Pacific Biosciences	0.1	2.2%

Notes:

(i) Market share represents each company's revenue from gene sequencing instruments, compatible consumables, and after-sales maintenance service in China's high-throughput gene sequencing instrument and consumables market.

Source: Annual reports of listed companies, JPM conference, expert interviews, CIC

According to CIC, the global EL-NGS testing market is estimated to increase from US$0.0 billion in 2024 to US$0.5 billion in 2033, representing a CAGR of 91.8% between 2024 and 2033. China's EL-NGS testing market is estimated to increase from US$0.0 billion in 2024 to US$0.2 billion in 2033, representing a CAGR of 77.0% between 2024 and 2033. The U.S. and EU EL-NGS testing markets are estimated to increase from nil in 2024 to US$0.1 billion in 2033, respectively. As of the Latest Practicable Date, no EL-NGS instrument had received regulatory approval, and all were marketed for RUO.

While establishing our domestic market presence in China, we plan to pursue international expansion by targeting key overseas markets such as the United States. With respect to the competitive landscape, the molecular testing markets in these targeted jurisdictions are dominated by a number of well-established players, each holding significant market share. There can be no assurance that we will be able to successfully compete with these market leaders or avoid being outperformed by them, given their dominant market positions and longstanding presence in the industry. For further details, please refer to "Risk Factors — We may not be able to develop new or improved products that are competitive in the market due to the intense market competition and the current dominance of certain key players, in a timely manner or at all."

Further Development and Commercialization Plan

We plan to actively pursue the clinical application of AxiLona AXP-100. We anticipate completing the type testing for the AxiLona AXP-100 in China in the second half of 2025, and subsequently commencing clinical trials. We also completed the design verification of our AxiLona AXP-100 in the United States in the second quarter of 2025, and plan to initiate the clinical trial in the fourth quarter of 2026.

We plan to continuously iterate and upgrade the AxiLona AXP-100 to enhance its capabilities and performance. Specifically, we plan to continuously optimize biochemical performance, enhance sequencing accuracy, establish multi-chip parallel processing capabilities, improve throughput, shorten detection process time, and reduce device size.

In addition, we plan to develop AxiLona AXP-1000, which would feature a higher throughput sequencing chip with ten million nanopore channels, offering nearly ten times the throughput of the AxiLona AXP-100. AxiLona AXP-1000 is currently in the design phase and we expect to complete the design of AxiLona AXP-1000 in the second half of 2026. AxiLona AXP-100 and AxiLona AXP-1000 may potentially be regulated as a single product by regulatory authorities. The two devices share substantial similarities in their overall architecture, biochemical technologies, functionalities, and applications. The primary distinction lies in the AxiLona AXP-1000's higher throughput through its more advanced chip. Regulatory authorities may view this as a functional scope expansion analogous to the protein detection capability added to the AxiLona EL-100, and consequently regulate both devices as a single product.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AXILONA AXP-100 SUCCESSFULLY.

Test Kits

Our test kits comprise biochips, reagents and other essential consumables. We are currently developing test kits for both of our molecular diagnostic products and EL-NGS platform. For example, we have been actively advancing development of specialized test kits for genetic detection and pathogenic microorganism detection. We anticipate completing design verification of the genetic detection test kits in the second half of 2025, and expect the pathogenic microorganism detection test kits targeting bacteria, viruses, and fungi to complete the design verification in the first half of 2026.

Test kits are designed to be used in conjunction with AxiLona EL-100 and AxiLona AXP-100 for both clinical applications and RUO purposes. The table below outlines the applications of the AxiLona EL-100 and AxiLona AXP-100 when paired with test kits in both clinical and research areas, and indicates whether corresponding test kits were developed in-house or by third parties.

	Clinical Applications[1]	Research Areas[1]	Identity of Collaboration Partner/Developer	Associated Medical Device
Test kits developed and/or being developed solely by us	X-linked monogenic disorders	/	Our Group	AxiLona AXP-100
	Multiplex respiratory pathogens (five targets)[2]	/		AxiLona EL-100
	Multiplex meningitis pathogens (seven targets)	/		AxiLona EL-100
		Multiplex respiratory detection panels (3-plex)		AxiLona EL-100
Test kits developed and/or being developed in collaboration with third party	/	Multiplex respiratory detection panels (16-plex)	A provincial center for disease control and prevention	AxiLona EL-100
		Single nucleotide polymorphism (SNP) detection for high-altitude adaptation	A university specializing in engineering and life sciences in China	AxiLona EL-100
		SNP detection for genetic disorders	A key clinical research institution under a major university hospital in China	AxiLona EL-100
		Detection of gastrointestinal pathogenic microorganisms	A leading research university in the United States	AxiLona EL-100
Test kits developed and/or being developed by third party	Detection of gene mutations	/	A biotechnology company located in Qingdao, China	AxiLona EL-100

Notes:

(1) Test kits for clinical applications differ from research-use-only (RUO) test kits in that the former are designed to assist in disease diagnosis and may be used by licensed medical institutions, whereas RUO test kits are intended solely for scientific research and experimental purposes, and their results cannot be used to guide clinical diagnosis or treatment decisions.

(2) The detection of multiplex respiratory pathogens (five targets) includes the detection of RSV.

Minor modifications and adjustments are required to adapt third-party test kits for use on our AxiLona EL-100 platform. These modifications include: (i) primer and probe adjustment, and (ii) electrochemical flap tag adjustment. Primer and probe adjustment encompasses customized probe design and primer synthesis. For example, within the AxiLona EL-100's nucleic acid detection capabilities, probes are used to detect and identify targets by carrying a labeled nucleic acid segment that hybridizes to the target sequence. Primers are oligonucleotides that initiate synthesis of new nucleic acid strands to enable sequence amplification. Electrochemical flap tag adjustment involves the use of an oligonucleotide bearing an electroactive label. Through a specific reaction, this releases a detectable tag fragment that modulates electron-transfer efficiency and generates a measurable current change, thereby enabling electrochemical nucleic acid detection on the AxiLona EL-100.

Though third-party developed test kits may be adapted for use in conjunction with our instruments with minor modifications and adjustments, our self-developed test kits offer distinct advantages. By leveraging our understanding of our instruments' technical features, we are able to pursue the development of test kits in a more rapid and cost-efficient manner. This positions us to address certain limitations of existing technologies, including in areas such as respiratory multiplex testing and meningitis detection.

Further Development and Commercialization Plan

Both our test kit for X-linked monogenic disorder and test kit for pathogenic microorganism are at the design verification stage. We anticipate completing the design verification for test kit for X-linked monogenic disorder in the fourth quarter of 2025, and initiating a clinical trial in the second quarter of 2026. We anticipate completing the design verification for test kit for pathogenic microorganism in the second quarter of 2026, and initiating a clinical trial in the fourth quarter of 2026. We have also entered into collaboration arrangements with third-party biotechnology companies for the joint development of test kits to be used in research areas, including multiplex respiratory detection panels (16-plex), SNP detection for high-altitude adaptation, SNP detection for genetic disorders and detection of gastrointestinal pathogenic microorganisms. Under the collaboration agreements, the development outcomes of the collaborative projects are typically owned by the partner company, while any patents arising from the joint development are co-owned by the partner company and us. The development cycle of a test kit varies depending on its intended application. For RUO test kits, the average development period is approximately six months. The development cycle of test kits for clinical applciations is expected to last approximately 21 months, comprising around nine months for pre-clinical research and 12 months for clinical research. The collaboration projects are currently under development in accordance with the agreed milestones and technical plans.

We plan to adopt a dual-channel approach for our test kits. First, we plan to conduct direct sales to tertiary grade A hospitals, KOL customers such as research institutions, clinical laboratories and government laboratories, as well as corporate clients. Second, we will sell through distributor channels to reach other medical institutions, research institutions and government laboratories. The potential end users of our test kits include hospitals, other medical institutions, research institutions, government laboratories, and biotechnology companies. In terms of marketing strategy, we will promote our products primarily through academic and professional engagement activities, including in-person seminars, product roadshows, and trial evaluations. We have participated in key

academic conferences such as the 22nd Annual Conference on Medical Genetics of the Chinese Medical Association held in Qingdao in November 2025, and intend to attend the Pathogen Detection and Infectious Disease Surveillance Academic Exchange Conference and the Frontiers in Genomics, Proteomics and Bioinformatics (GPB) Symposium in 2026 to strengthen market presence and academic recognition. With respect to pricing, we plan to adopt a cost-plus and market benchmarking pricing strategy.

At this stage, our regulatory registration plan for clinical-use test kits is focused in China. Research-use-only (RUO) test kits, once developed, may be used in China, the United States, and the European Union for scientific research purposes. We are currently prioritizing obtaining regulatory approvals for our test kits in China as successful commercialization of our instruments will partially depend on the availability of compatible test kits. In the United States, given the more established LDT framework, we plan to introduce our instruments through collaborations with downstream application developers and clinical institutions under the LDT pathway, which allows market introduction of our instruments without the immediate need for FDA registration of the associated test kits.

Services and Other Products

Synthetic Biology and Chemical Engineering Services

We provide synthetic biology and chemical engineering services, which are part of our biotechnology services primarily aimed at biotech companies. One of our key offerings is custom synthesis of chemical products, which involves tailored small molecule synthesis, optimization, and enhancement of biological activity for biomedical research and industrial applications. This service has been fully developed, and we have already delivered two batches of products to clients in 2024.

Another service we offer is high-throughput protein mutagenesis services, which includes gene synthesis, mutant library construction, protein expression and purification, high-throughput screening of mutants, and sequence validation. This service has also been fully developed and is available for external use to facilitate specific needs.

Multi-omics Detection Solutions

Leveraging our EL-NGS platform technology, we are developing service solutions for multi-omics protein detection. These potential offerings include our ELP solution for multiplex protein marker detection built on the EL-100 platform and our AXPP solution for protein sequencing based on our EL-NGS platform. The development of these solutions is part of our long-term strategy to extend our core platform capabilities. Together, these interconnected platforms establish a unified framework for comprehensive multi-omics detection solutions.

Non-invasive Saliva Glucose Monitor

Building upon our proprietary electrochemical detection capabilities, we have developed a consumer-focused non-invasive saliva glucose monitor designed for

home-use POCT. This saliva-based blood glucose monitoring solution enables users to obtain clinical-grade glucose readings through simple oral fluid collection, eliminating traditional blood sampling requirements. Notably, we have entered into a collaboration arrangement with an industry-leading research institute for further development, demonstrating market validation of both our technology and R&D competencies.

AxiLona Library Preparation Robotic System

The AxiLona Library Preparation Robotic System represents our next-generation robotic platform for genomic workflow automation. It features precise liquid handling with automation capable of pipetting as low as 1μL, achieving a precision coefficient of variation (CV) as low as 0.5%.

The robotic system is equipped with a pipetting arm with up to eight channels that offers full-range pipetting, ensuring accuracy, efficiency, and flexibility. It utilizes capacitive and pressure sensing technology to detect liquid levels, clots, air gaps, and pipette tips, enhancing reliability and preventing errors. The system also includes automatic needle installation and removal, providing real-time monitoring for improved needle removal efficiency and preventing contamination.

For high-efficiency library construction, the system integrates PCR, magnetic rack, temperature control, and anti-contamination modules. It automates the entire library preparation process, enabling the construction of eight samples per batch. This automation reduces labor requirements, which based on our internal testing, can reduce labor time by approximately 50% compared to manual methods. Laboratory validation has shown that the library yield and read length distribution produced by the AxiLona Library Preparation Robotic System are consistent with manual preparation, ensuring the same high-quality results.

We have established a collaboration with a specialized liquid handling module manufacturer who will supply the robotic components and corresponding consumables under the relevant contract terms to us. We will enjoy the ownership of the patents related to such robotic system developed through this partnership mode. In the future, we may forge additional partnerships with other industry players or suppliers to further enhance the automation and portability of sequencing workflows of our AxiLona Library Preparation Robotic System.

RESEARCH AND DEVELOPMENT

Our ability to compete depends largely on our continuing commitment to research and development, and our capabilities to create new technologies, design new products, and enhance existing products. We have comprehensive R&D capabilities, with core technologies developed in-house, allowing us to cover subsequent product development process with low external dependency. In 2023, 2024 and the six months ended June 30, 2024 and 2025, we incurred research and development expenses of US$15.3 million, US$11.4 million, US$6.1 million and US$4.5 million, respectively. For details, please refer to "Financial Information — Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income — Research and Development Expenses."

Our comprehensive proprietary portfolio spans instruments, test kits and services. As of the Latest Practicable Date, we have one product approved for registration by Jiangsu MPA, namely our Core Product, AxiLona EL-100. We are actively exerting substantial R&D efforts to unleash the clinical application potential of our pipeline products, such as the ongoing clinical trial and continuous upgrade of existing versions. Also, we have been engaging in and will continue to focus on R&D for our RUO products to expand our research-use customer base and increase customer stickiness. Further, we are continuously expanding our product and service offerings leveraging our foundational technology platforms.

Our Technology Platform

We focus on developing life science technology platforms, with core expertise spanning four key areas: integrated circuit chips, synthetic biology and chemical engineering, electrochemistry and microfluidics, and artificial intelligence. These technologies are inherently integrated and functionally interdependent, together forming the technological foundation for our products. This structure systematically drives the performance, cost-effectiveness, and innovation of our solutions. The primary hurdles facing our technology platforms include their technically challenging nature and R&D-intensive requirements. The complexity of the technology demand substantial investment in both expertise and resources to continuously overcome development barriers.

These technologies are designed to work in concert to deliver a complete solution, from sample processing to data interpretation. Their functional relationship is as follows:

- ***Integrated Chip Technology***: Our integrated chip technology consists of arrays of electrochemical sensors operating in current-sensing mode for biomarker detection. Both the EL-100 and AXP-100 chips are based on the same core principle: sample → electrochemical detection → signal processing. They perform massively parallel transduction of chemical signals into measurable electrical signals on a single chip, enabling versatile operation and highly sensitive detection. In addition, both chips integrate microfluidic components that facilitate sample preparation and reagent-liquid interaction.

- ***Synthetic Biology and Chemical Engineering***: Engineers the essential biochemical reagents for the sensing platform. This involves creating specialized components, such as optimized polymerases and modified deoxynucleoside triphosphates (dNTPs). These custom-developed reagents are specifically designed to generate the precise chemical signals that are subsequently detected and translated by the chip.

- ***Electrochemistry and Microfluidics***: Provides the core physical interface for the on-chip biochemical reactions. It combines microfluidics for the precise manipulation and delivery of samples and reagents with electrochemistry to create a stable environment for signal generation and measurement. This integration ensures accuracy and reproducibility.

- ***Artificial Intelligence***: Functions as the core data processing and interpretation engine of the system. It employs machine learning models to de-noise, filter, and accurately classify the raw electrical data stream from the chip's sensor array. This sophisticated signal processing is essential for translating the raw data into an accurate and interpretable genetic information and improves R&D efficiency in related biochemical fields.

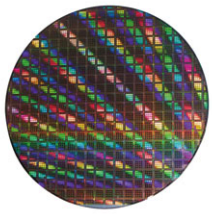
Our full-stack, in-house development model is built on the close integration of IC (Integrated Circuits), BT (Biotechnology), and AI (Artificial Intelligence). We design our products including AxiLona EL-100 with capabilities across our platforms each element: our Biotechnology generates a specific chemical reaction, our IC Chip is optimized to efficiently convert that reaction into a digital signal, and our AI accurately translates that signal into a final result. This tight integration allows us to systematically optimize the entire workflow, achieving a high degree of performance and data reliability. The development of our Core Product, AxiLona EL-100, exemplifies our full-stack in-house development capabilities. AxiLona EL-100 was designed entirely in-house, with exclusive ownership of intellectual property rights. It integrates our internally developed hardware, electrochemical system, and software. We have completed clinical trials for AxiLona EL-100 and obtained device registration approval.

Integrated Circuit Chip Technology

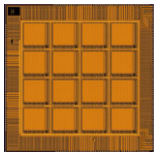
Features and Competitive Strengths of Our Chip Technology

The cornerstone of our products is our proprietary, integrated circuit (IC) grade biochip. According to CIC, we are among the few companies in the molecular testing industry with a semiconductor R&D team, who possess extensive experience in advanced semiconductor process design and manufacturing focused on integration with bio liquids. Specifically, the EL-100 chip is a distributed electrochemical sensor with analog detection. Meanwhile, the gene sequencer requires comprehensive detection with higher throughput data; therefore, the AXP-100 chip integrates electrochemical sensors with CMOS circuits on a silicon chip. Our independently developed semiconductor biochip, microfluidic Bio-CMOS chip, serves as the core component of our EL-NGS gene sequencers and other molecular diagnostic products. Our integrated chip technologies share a common technological architecture, creating strong synergies across research and development, manufacturing, and product expansion. It employs our proprietary design and signal processing and forms the foundation of our high-throughput, low-cost, and precise detection and molecular diagnostic products.

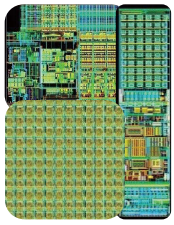
Below are pictures demonstrating our wafer, Bio-CMOS chips and integrated circuit.



Wafer



Bio-CMOS chip



Integrated Circuit

Gene sequencing and molecular diagnostics chip technology is moving from conventional chips that rely on external equipment to the highly integrated chips. Traditional chips primarily provide passive reaction wells, while critical signal detection depends on large optical systems. Our integrated circuit chip technology enables the chip itself to perform direct electrical signal reading, analog-to-digital conversion, and digital output.

Our self-developed microfluidic Bio-CMOS chip is the globally first 300mm, 65nm process Bio-CMOS chip with one million channels. The chip has successfully completed tape-out, full system validation, and scaled mass production. Key features and advantages of our proprietary Bio-CMOS chip include high throughput and reduced costs, high precision with low noise, and compatibility with standard semiconductor processes, making it highly scalable.

In addition, when benchmarked against market-leading sequencing chips, such as the ONT PromethION series (with average observed accuracy of 96.8% for R10.4.1 and 2,675 channels per flow cell), our proprietary semiconductor sequencing chip, designed with a 12-inch 65nm process and incorporating millions of parallel sequencing units, delivers enhanced sensitivity and accuracy of up to 99%. These differentiating features reflect our ability to provide more precise, reliable and cost-effective sequencing solutions compared to incumbent.

Our Independent Research and Development

We commenced the R&D of our proprietary Bio-CMOS chips in 2016 and have independently developed our core technologies and know-how. Our development process follows a structured, multi-stage iterative methodology, progressing from initial concept validation to a fully integrated, mass-producible commercial chip. This process, protected by our patents and know-how, creates significant entry barriers.

- ***In 2016: Initial Proof-of-Concept.*** We developed our first prototype, a passive test chip. This chip was designed to validate our fundamental concepts, including nanopore insertion and microfluidic control, and was fabricated at an academic research facility.

- ***In 2017: Scaled Validation Prototype.*** We developed a second-generation passive prototype that scaled our design to approximately one million sensor cells. Fabricated using a commercial 65nm foundry process, this chip was crucial for validating our core sensor cell architecture and microfluidic systems in a high-density format, confirming its suitability for mass production.

- ***In 2018: Completion of our proprietary Bio-CMOS sequencing chip process integration.*** We achieved a major technological breakthrough with the successful tape-out, testing, and system-level validation of our AX001 chip. This is our first fully integrated, commercial Bio-CMOS production chip, which integrates over one million active sensing cells with on-chip analog amplification and digital signal processing circuits on a single die. This milestone established our proven capability to design and mass-produce highly advanced, integrated biochips.

Our chip development, testing, and manufacturing processes incorporate a range of proprietary technologies that are critical to performance, stability, and scalability. Our design process follows a systematic, industry-standard methodology for both front-end (architectural and logical design) and back-end (physical layout and verification) development. We conduct comprehensive, multi-level testing from individual components to full system verification using biological samples. In the R&D and production of our chips, we collaborate with third parties, including wafer manufacturers and electronic design automation (EDA) tool providers. This collaboration leverages their mature manufacturing capabilities and standardized design tools, while we retain our core intellectual property, including the chip architecture, proprietary circuit designs, and know-how.

The process of developing and iterating semiconductor chips is highly complex, requiring a deep integration of expertise from multiple fields such as semiconductor engineering, biochemistry, microfluidics, and algorithms. While high-density chip integration may face inherent technical complexity in balancing precision fabrication and yield, our established semiconductor design expertise and proven track record of mass production provide strong safeguards for scalability and reliability, which create challenging entry barriers for our competitors. According to CIC, the Group's Bio-CMOS chip represents a significant technological advancement in the field of molecular diagnostics and gene sequencing. The key differentiating factors and competitive strengths are summarized as follows:

- *Comparison with Market Peers*. Compared to other advanced high-throughput sequencing chip in the market, the Group's Bio-CMOS chip achieves a substantially higher degree of parallelism and data throughput potential. For instance, while a leading competitor's flagship system may integrate approximately 144,000 measurement channels, the Group's chip is designed to integrate up to 1,000,000 independent detection units on a single chip.

- *Applications and Customization*. The technology is primarily applied in advanced DNA sequencing. The underlying semiconductor platform allows for a high degree of customization in the design and layout of the sensor arrays to meet specific performance and application requirements.

- *High Entry Barriers*. The development of such integrated chips is highly complex and creates significant barriers to entry for competitors. These barriers are attributable to the need to seamlessly integrate deep, specialized expertise across multiple disciplines — including microelectronics, molecular biology, surface chemistry, and advanced signal processing — as well as the significant capital investment required for research, development, and fabrication.

Our proven microfluidic chip design and manufacturing capabilities distinguish us from our competitors, allowing us to maintain technological superiority and secure a competitive position in the market.

Shared Technology Across Our Products

Our core integrated chip technology and associated know-how form a versatile and scalable foundation that is leveraged across our different products, including our AxiLona EL-100 and AxiLona AXP-100. This shared technological architecture creates synergies in research and development, manufacturing, and product expansion. The key commonalities include:

- ***Instrument Architecture.*** Both products are based on a similar overall system design, which includes a standardized loading module for our chips and cartridges, a fluidic control system using pumps and valves, and an electrical interface that uses a socket to connect the chip to a main control board for signal processing.

- ***Core Detection Method.*** Both products utilize the same fundamental electrochemical detection method, which is a core element of our proprietary chip technology.

- ***Sample Preparation.*** The workflows for our test kits, particularly for sample preparation steps such as nucleic acid extraction and amplification, are also shared between the products.

This technological overlap is protected by our intellectual property portfolio. Among our granted and pending patents, 18 patents cover technologies and methods that are common to both our AxiLona EL-100 and AxiLona AXP-100.

Synthetic Biology and Chemical Engineering Technology

Our independently developed synthetic biology and chemical engineering platform is designed to achieve full in-house research, development, and quality control over the critical reagents that underpin our products. This capability systematically supports our gene sequencing and molecular diagnostics products by enhancing performance while controlling quality and cost. The platform is equipped with comprehensive synthesis and analytical instruments, as well as a rapid high-throughput automated system supporting the full range of biological synthesis tasks, including small molecule building block synthesis, DNA synthesis, post-synthesis modifications, purification, and analytical testing. Although optimizing core reagents often involves trade-offs between speed, fidelity and stability, our algorithm-assisted enzyme engineering and high-throughput screening platforms enable us to efficiently achieve balanced performance across multiple parameters, ensuring high-quality and reproducible results. Key capacities of our synthetic platform include:

- ***Modified dNTP synthesis.*** The chemical reagents used during the workflow of our devices are critical to the performance of our products. The design of our synthetic biomarkers directly correlates to the resolution and clarity of the output signal, while the purity achieved in our synthesis process is essential for the precision of the detection chemistry.

- ***Custom synthesis.*** Our platform provides customized synthesis of DNA, RNA, various standard and modified phosphoramidites, and oligonucleotides. The resulting products feature (i) high purity (≥98% for HPLC main peak area and mass spectrometry analysis), (ii) high synthesis capacity (up to 1 mmol per batch), and (iii) stable quality. This platform also provides customized capture and detection probes that are integral to our electrochemical detection technology. This enables us to develop test kits for various uses and modify third-party test kits to work with our system.

- ***Enzyme engineering.*** Polymerase is a core bioactive agent fundamentally dictates the performance of our molecular diagnostics products. For example, the detection of AxiLona EL-100 process employs PCR polymerase. For our sequencing system, naturally occurring enzymes often do not meet the stringent, multi-dimensional requirements of our products, such as high thermal stability, rapid reaction speed, high fidelity, salt tolerance and strong template-binding affinity. To address this, we have developed our proprietary enzyme engineering technologies, including (i) a microfluidics-based high-throughput protein screening and evolution system, capable of screening approximately 10^5 to 10^6 random mutants, and (ii) a protein rational design platform driven by AI algorithms, sequence analysis, and critical site analysis. By combining high-throughput screening with the rational design of key protein sites, we can efficiently discover and engineer polymerases with superior properties for production, enhancing the overall performance and market competitiveness of our sequencing products.

Synthesis Lab

Solid-Phase Synthesis Facility

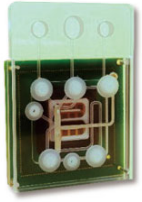
Analytical Lab

Our Laboratories for Synthetic Biology Services

According to publicly available information and third-party quality inspection reports, comparable products from other market players generally show polymerase purity levels of over 90% for Sigma-Aldrich (KOD DNA polymerase) and 95% for a Chinese company engaged in the development of molecular, protein, and cellular biology reagents (Tth DNA polymerase). In addition, while certain oligonucleotide products, such as ORF-1 from a Chinese company dedicated to the development of synthetic genomics and biosynthesis products, achieve a main peak area ratio above 95% under HPLC testing, other suppliers, such as a Chinese company focused on providing upstream raw materials, consumables, and services for life sciences, do not guarantee purity levels. Against this backdrop, our proprietary reagents are developed through a systematic platform that ensures high fidelity, stability and consistent quality, thereby delivering competitive advantages in sequencing applications.

Electrochemical and Microfluidic Technologies

The integration of electrochemical biosensor technology with a precision microfluidic system in our Bio-CMOS chip is foundational to the sophisticated sequencing cartridges used in our instruments. This design enables efficient, synchronous reactions that generate clearly identifiable electrical signals. Below is a picture showing the cartridge used in our instruments:



Cartridge

The combination of electrochemical and microfluidic technologies brings multiple advantages:

- ***Ultra-low cost.*** By not requiring expensive and complex optical components, electrochemical detection significantly reduces costs for both instruments and test kits compared to other methods. This makes it highly accessible for widespread applications.

- ***High throughput.*** The scalability of electrochemical detection allows for the development of high-density detection arrays, and our architecture is designed to support the continuous increase in the density of sensing electrodes.

- ***High accuracy.*** Electrochemical detection provides enhanced sensitivity by generating direct and rapid signals with minimal signal loss, which is further augmented by our use of innovative electrode materials. Our system achieves high specificity by enabling the simultaneous use of multiple nucleic acid fragments from the same target DNA or RNA molecule. This ensures reliable and precise measurements in all intended use of our devices under development, including nucleic detection and protein detection on AxiLona EL-100 and gene sequencing on AxiLona AXP-100.

- ***Portability.*** Unlike optical signal detection methods, electrochemical detection eliminates the need for bulky optical components, enabling the miniaturization and portability of gene sequencing devices. This facilitates the development of compact and portable products.

- ***Fast turnaround time.*** The direct readout of electrical signals allows for faster detection and higher efficiency, significantly reducing the time required for analysis compared to more complex detection methods.

By combining electrochemical biosensor technology with microfluidic precision, the integrated chip represents a technological advancement in cost-effective, high-throughput, accurate, portable and fast detection solutions, making it ideal for a wide range of applications, including molecular diagnostics and gene sequencing. We recognize that microfluidic circuits at micro- and nano-scale can be sensitive to channel clogging or evaporation. However, our proprietary design and validation processes have demonstrated robust fluidic stability, supporting consistent high-throughput applications.

AI-Enabled Capabilities

Our AI capabilities support the development of biological components and the analysis of sequencing data. We use proprietary AI models trained on our R&D data to improve the design of enzymes and analysis of sequencing results.

AI-Enhanced Biological Component Development

Our AI capabilities enhance our synthetic biology and chemical engineering expertise. Databases linking protein sequences with structures, combined with AI technology, have accelerated protein design for creating customized enzymes, protein-based drugs, vaccines, and drug delivery vehicles. Based on our platform technologies, we have independently developed multiple synthetic biology and chemical engineering platforms, including high-throughput automated protein screening systems and rapid high-throughput small molecule automated synthesis systems. These platforms enable us to optimize biological protein activity, enhancing the performance of synthetic products.

Through AI integration, we can achieve better engineered modeling of polymerases, nanopore proteins, and sequencing complexes through various methods including identifying key sites and improving enzyme modeling. We have established mutation libraries of target genes based on microfluidic PCR, enabling protein-directed evolution through Compartmentalized Self-Replication, with screening throughput of approximately 10^5-10^6 random mutants.

This AI-driven platform for high-throughput protein screening and directed evolution, which systematically accelerates the discovery of novel proteins with enhanced performance, consists of the key stages including AI-guided mutant library design, microfluidic-based high-throughput screening, AI-driven screening and sorting, and iterative model optimization.

This AI-driven platform enhances our ability to develop proprietary reagents that are crucial to the performance of our products. For example, in a project to engineer certain polymerase with enhanced salt tolerance, we employed this system to screen a large mutant library. After two to three rounds of this iterative "design-screen-learn" cycle, we successfully developed a proprietary polymerase with a four-fold improvement in activity under high-salt conditions. This capability provides us with a significant competitive advantage by enabling us to create superior biological components tailored specifically for our technology platforms. While algorithm training requires extensive datasets to ensure robustness across diverse clinical samples, our proprietary data assets accumulated from years of experimentation provide a unique advantage in mitigating bias and supporting accurate real-world performance.

AI-Driven Data Analysis and Interpretation

Our proprietary AI and bioinformatics platform is important to our product performance, enabling the rapid and accurate interpretation of complex biological data. A core function of our platform is to translate the raw, complex electrical signals generated by our nanopore detection cells into highly accurate genomic data. This is accomplished through a synergistic integration of our hardware with AI algorithms that facilitate predictions, pattern recognition, and data integration.

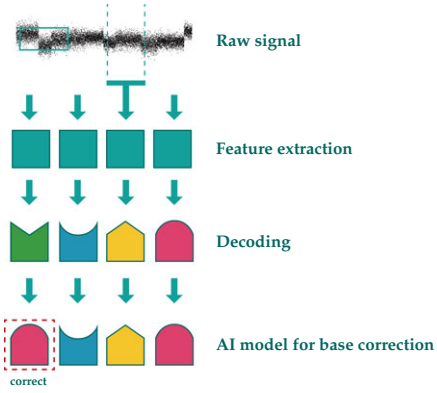
Deep Learning for High-Accuracy Base Calling

Our primary base calling algorithm utilizes a Transformer-based deep learning architecture. Trained on millions of proprietary experimental data points, it decodes the

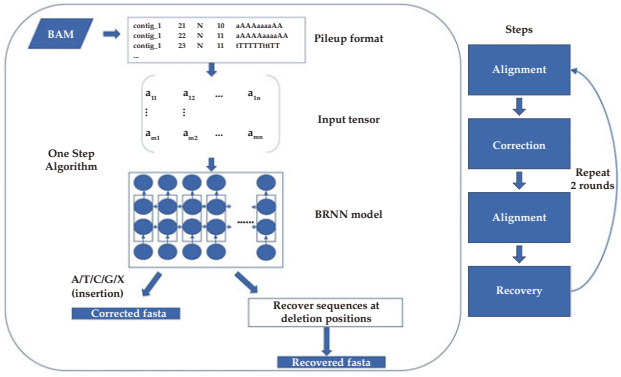
characteristic electrical signal patterns generated as different DNA bases passing through our nanopore sensors. Our adaptive filtering algorithms denoise signals, and a deep correction model optimize consensus sequence accuracy for circular sequencing. We have also developed and patented new sample preparation methods for both single-stranded and double-stranded DNA based on these AI-related capabilities to enhance sequencing accuracy.

Advanced Bioinformatics Applications

Through a research collaboration with Peking University and Inner Mongolia Agricultural University, we have developed MetaCONNET, a novel metagenomic assembly tool. This tool leverages neural network-based machine learning models and specializes in error correction for long-read sequencing data in metagenomic assemblies, delivering superior performance across key metrics including accuracy, coverage, contiguity, and resource consumption in academic studies. Below is the workflow of our deep learning-based base recognition algorithms and the neural network-based machine learning model powering our MetaCONNET platform.



Workflow of Deep Learning-based Base Recognition Algorithms



Neural Network-based Machine Learning Model

Source: MetaCONNET: A metagenomic polishing tool for long-read assemblies, Dec 2024, PLOS ONE

In addition, by analyzing complex biological signals, such as ctDNA methylation patterns or metagenomic data from pathogens, AI algorithms can facilitate the early detection of cancers and the rapid identification of infectious agents. This capability contributes to more automated, sample-to-result sequencing workflows.

Product Development Cycle

We have built an in-house R&D management system. This management system enables our R&D activities to effectively align with the customers' needs and expectations based on regular interactions with customers and in-depth market research. Leveraging the seamless collaboration among different functional groups, we are able to deliver products with high quality to address market needs. Our product development process typically involves the following steps:

- *Product proposal and approval.* We typically collect thorough information related to market trends and demands before initiating a new product development project. Our product development cycle starts with a preliminary development proposal that describes unmet needs, research areas, key technologies and potential risks. Such a proposal is then assessed by multiple functional teams to consider technical feasibility, manufacturability, market potential, budget, and other critical variables. After that, a finalized product proposal is prepared for internal review by our management team, who will decide whether to proceed with the proposed project.

- *Product design and development.* After our management team approves the project, we will formulate a detailed development plan covering the product functionalities and applications, as well as labor and budget planning, and then commence the development process. Our new product design and development will strictly follow our internal control protocol prepared with reference to the risk management standards under GMP and ISO 13485:2016, among others. For details, please refer to "— Quality Control" in this section.

- *Product testing and validation.* All products will go through several rounds of internal testing and external file tests. Our management team will collect comprehensive feedback so that we can refine our designs, resolve technical issues and fix technology bugs. In addition, some of our products for clinical use are required to be validated in clinical trials in the relevant jurisdictions. For details, please refer to "— Research and Development — Clinical Development" in this section.

- *Launch.* In compliance with industry norms, we typically launch our products for RUO purpose after passing strict quality control checks, and continue to supervise their production and sales. For certain products for clinical use, we will launch them after receiving the relevant regulatory approvals, which vary in different jurisdictions. For details, please refer "Regulatory Overview."

Our Research and Development Team

As of the Latest Practicable Date, we had assembled a sophisticated and stable R&D team comprised 75 members with multidisciplinary backgrounds and industry know-how across semiconductor, biotechnology and artificial intelligence, around 60% of whom hold doctorate or master's degrees. Compatible with our global operations, we have R&D centers located in both China and the U.S. Our R&D team is led by our visionary and seasoned senior management. Our founder and CEO, Dr. Tian, is a leading scientist who is the inventor of over 100 granted patents globally, with more than 20 years of experience in the fusion of biotechnology and semiconductor. Dr. Tian obtained a bachelor's degree in applied physics with a minor in business management and a master's degree in engineering physics from Tsinghua University (清華大學) in the PRC in July 1993 and July 1996, respectively. He also obtained a master's degree in electrical engineering and a PhD degree in applied physics from Stanford University in the United States in January 1999 and September 2000, respectively. Before founding our Group, Dr. Tian served leadership roles at global pharmaceutical multinational company, and Silicon Valley technology companies such as InVisage Technologies Inc. (a fabless semiconductor pioneer acquired by Apple Inc. in 2017 and known for QuantumFilm, a quantum dot-based image sensor technology) and Aptina, positioning him as a pioneer in the convergence of biotechnology and information technology. Our founder and COO, Dr. Ivanov, is a successful serial entrepreneur with extensive R&D experience and founded multiple biotech companies. As an inventor of over 100 granted patents globally, his expertise in nanomaterials and semiconductor, honed through previous career at InVisage Technologies Inc., Intermolecular (an advanced material innovation company which later went public on Nasdaq and subsequently acquired by Merck KGaA.), Blue29, CuTek and Mattson, provide valuable insights into our technological advancements and potential commercial success. For details, please refer to "Directors and Senior Management."

Our R&D team members possess strong academic backgrounds, having received professional education from world-renowned institutions such as Stanford University, Yale University, Purdue University, and Peking University. Our biochemistry and product integration team comprises professionals who have spearheaded gene sequencing or molecular diagnostic product development at prestigious entities such as Life Technologies (acquired by Thermo Fisher), the U.S. CDC, the Translational Innovation Center of Shenzhen Bay Laboratory, BGI and various nanopore sequencing companies. Our hardware and electronics team is made up of seasoned professionals with deep technical expertise, including IC design veterans, micro-electromechanical systems and nanotechnology experts, and software engineers specializing in medical device and AI-driven medical imaging system development.

We have entered into labor contracts with intellectual property assignments, confidentiality and non-compete provisions with all of our employees, pursuant to which intellectual property conceived and developed during their employment belongs to us, and all relevant rights or claims to such intellectual property are waived.

Clinical Development

We conduct clinical trials of certain product candidates if required by applicable laws and regulations. For details, see "Regulatory Overview — Relevant Laws and Regulations in the PRC — Regulation of Medical Devices — Clinical Evaluation and Clinical Trials of Medical Devices." We have professional personnel responsible for our in-house clinical development process, the duties of which include selecting clinical trial institutions, designing clinical trials, supervising CROs, monitoring clinical progress, and preparing materials for regulatory purposes.

Collaboration with Clinical Trial Institutions

The NMPA maintains a catalog of hospitals registered as clinical trial institutions, from which we select a number of leading hospitals to conduct our clinical trials. The factors we commonly consider when selecting institutions include their credentials, expertise, academic influence and background, infrastructure, equipment and patient demographics. We also meet with potential investigators to discuss the purpose and requirements of our clinical trial. After comprehensive evaluation, we and the institution generally enter into an agreement setting out the clinical trial's purpose, timeline, procedures, methods and risks. We then work together with the principal investigators to obtain an opinion from the institution's ethics committee. The clinical trials must be conducted in accordance with the protocol approved by the ethics committee. Any amendments to the protocol must be re-evaluated and approved by the ethics committee.

During the Track Record Period, we cooperated with two clinical trial institutions in China for the clinical trial of our Core Product, including Zhejiang Provincial People's Hospital (浙江省人民醫院, which was the leading site) and Yichang People's Hospital (宜昌市人民醫院).

Pursuant to the agreements with these participating clinical trial institutions, the institutions are required to conduct the clinical trials strictly in accordance with the protocol, to collect data, and to issue trial reports at the end of each clinical trial. The lead institution will prepare formal reports based on the trial reports submitted by all participating institutions. In return for the institutions' services, we make scheduled payments as specified in the agreements. Under the agreements, we generally own all the intellectual property in relation to the clinical trial while the participating institutions may publish or otherwise use the clinical trial results for academic activities with our prior approval.

We maintain close communication with principal investigators involved in clinical trials, who are mainly reputable physicians and researchers in the clinical institutions, to better understand the performance of our product candidates and resolve any issues that might come up during clinical trials. We believe communication and suggestions from principal investigators from a clinical perspective are valuable to us in adjusting our registration plan and upgrading our design and development of product candidates.

Relationships with CROs

We collaborate with reputable CROs to conduct and support of our clinical trials. We select CROs by weighing various factors, such as their qualifications, expertise, experience, reputation and costs. We generally enter into an agreement with the CRO for each clinical trial. The CROs must comply with all applicable laws and regulations as well as follow our protocols to ensure that all clinical trial results are accurate and authentic. For the development of our Core Product, we collaborate with one CROs to conduct clinical trials.

Under the agreements with our CROs, we are responsible for trial protocol design and supervision of the trial progress, while the CRO takes responsibility for trial preparation, test sample collection, trial implementation and management, record keeping and report preparation to guarantee the compliance of the clinical trial process with applicable regulations or standards. In return for their services, we make scheduled payments as agreed in the agreements. Under the agreements, we generally own all intellectual property and trial results and the CROs must maintain strict confidentiality with respect to the information they acquired from us during clinical trials.

Collaboration with Third Parties

Besides collaborations for the purpose of clinical trials, we have developed strategic alliance and collaboration with renowned partners, facilitating scientific discoveries and technical advancements. For example, we collaborate with prominent universities, research institutes and hospitals, including Peking University, Guangzhou University, Huazhong University of Science and Technology and Inner Mongolia Agricultural University in the form of research projects, in which we are deeply involved in the major research and development activities. Under the collaboration agreements, the intellectual property rights arising from these research projects are either solely owned by us or co-owned, while specific ownership terms may be negotiated on a case-by-case basis. Collaborations with these third parties tightens customer relationships, keeps us informed of market demands and leading-edge technologies, and inspires us to continuously improve our products. Below is a summary of the key terms of the collaboration agreements with third parties.

Category of Terms	Summary of Typical Terms
Scope and Services	The Company typically engages a partner (e.g., a CRO or university lab) to perform specific, non-core R&D services. These services are provided on a non-exclusive basis. The partner provides its technical expertise and services, while the Company provides the necessary materials, equipment and research direction.
Term	The term is generally project-based, terminating upon completion of the project or delivery of the agreed-upon results. Some agreements may have a typical fixed term of two years, subject to renewal by mutual consent.
Payment Terms	Payments are structured primarily on a fee-for-service basis or upon the achievement of specific, technical milestones. The Company pays a fixed fee to the partner in consideration for the services rendered. These agreements do not involve any profit or revenue sharing arrangements.
Intellectual Property Rights	The Company retains ownership of all its background intellectual property. For new technology resulting from the collaboration that is independently developed by the partner and unrelated to the Company's core technology, the IP rights are typically owned by the partner. For jointly developed IP, ownership is determined based on the respective contributions of each party. All agreements explicitly provide that any improvements or inventions related to the Company's core technology platform remain the exclusive property of the Company.
Confidentiality	Both parties are subject to strict confidentiality obligations and may not disclose the existence of the agreement, its terms, or any confidential information of the other party received during the collaboration. This obligation generally survives the termination of the agreement for two to ten years.
Governance and Termination	Due to the non-strategic nature of these collaborations, the agreements typically do not establish a joint steering committee or similar complex governance mechanisms. Either party may terminate the agreement under certain conditions. During the Track Record Period, the Company has not terminated any material collaboration agreement prematurely.

MANUFACTURING

Manufacturing Facilities and Production Capacity

We manufacture, assemble and test our products mainly at our 4,100 square-meter manufacturing center in Wuxi. We had three production lines, with an annual designed production capacity of 1,000 units of instruments and 100 thousand sets of test kits. Our manufacturing facility is designed to be in compliance with GMP requirements of China and applicable regulations in the EU. We are also accredited in accordance with the ISO 13485 quality standard. As of the Latest Practicable Date, we had a manufacturing team of 19 employees. We have received the medical device production permit for AxiLona EL-100 from Jiangsu MPA in April 2025. Leveraging our own production lines and in-house manufacturing personnel, we do not rely on any imported products or external CMOs. We plan to build a new production line for our instruments and test kits to expand our manufacturing capability to capture the growing market demand.

The machines we use to manufacture our instruments and test kits mainly include, among others, air conditioning and purification system, purified water system, comprehensive electrical safety performance tester, plasma cleaning machine, spotting instrument, vacuum packaging machine, fluorescence quantitative PCR instrument, microscope, ultra-low temperature refrigerator. We purchase machinery from multiple suppliers, and we are able to purchase manufacturing machinery from alternative suppliers. As of the Latest Practicable Date, we owned all the equipment used in our production processes, including laboratory equipment and instruments. We perform routine and preventative maintenance on our manufacturing machinery and equipment to ensure their proper functioning. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material interruption to our production process due to machine or equipment failure.

We believe that our current manufacturing capacity is able to meet our short-term commercial needs. In addition, we have access to China's vast labor pool, which makes it easier for us to hire people with the appropriate skills for our production. Typically, we require new employees to undergo two to four weeks of training before they commence work on our production lines. The training continues with respect to specific steps in the production process after employees commence work on the production lines. The comprehensive training enables us to increase our capacity utilization rate and our product yield rate, which as a result enhances our manufacturing efficiency.

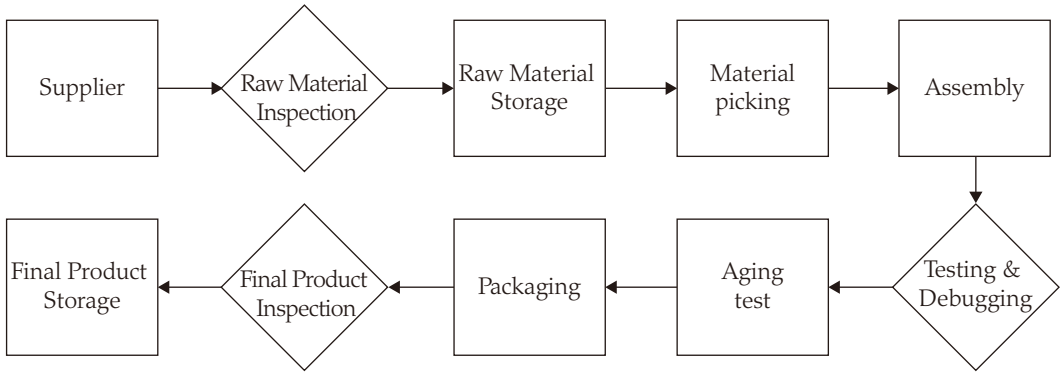
Our Manufacturing Team

We have a strong and specialized manufacturing team, well positioned to bring proprietary technologies or processes into GMP production. Our manufacturing team has abundant experience in medical device manufacturing and quality control. As we progress the commercialization of our Core Product, we will further expand our manufacturing team to meet the anticipated increase in the sales of our Core Product along with relevant test kits. We provide regular training to our manufacturing personnel to ensure that they possess the skill sets and techniques required in the relevant manufacturing process and comply with our quality control requirements as well as applicable laws and regulations.

Production Process

Production Process for Our Instruments

The following diagram illustrates the production process for our instruments.



The following is a brief description of the key steps in our manufacturing process of instruments.

- *Preparation of raw materials.* We procure raw materials from multiple suppliers to satisfy subsequent production steps. Following receipt, we inspect these materials to ensure they meet our quality standards before storing them in appropriate warehouses. Upon retrieval from the warehouse, materials are temporarily stored in the production area until needed. Materials with electrostatic discharge sensitivity undergo appropriate anti-static handling procedures. All instrument assembly operations are conducted in controlled cleanroom environments to ensure product quality and prevent contamination.

- *Modular manufacturing.* We produce major product parts in modular and standard procedures to efficiently manufacture standardized components that can be assembled into different end products.

- *Assembly.* Product components and parts are assembled according to the requirements of our production operation manual.

- *Testing.* We test the functionality of such components and products according to applicable testing standards.

- *Aging.* We conduct product aging tests to observe how product properties change over time, ensuring that products maintain their safety and efficacy even after extended storage periods.

- *Packaging.* We pack our products in compliance with sterile integrity and regulatory standards.

- *Inspection.* We conduct final inspection of our finished products according to applicable inspection standards and regulations.

Production Process for AxiLona EL-100

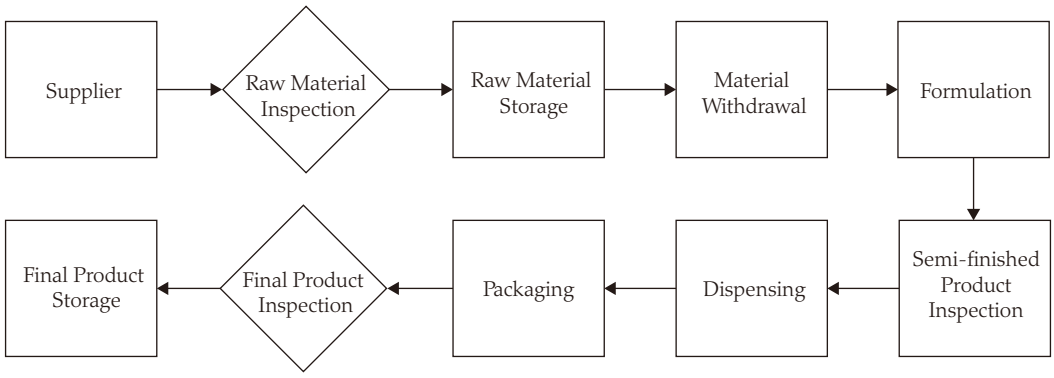
The AxiLona EL-100 microarray chip analyzer consists of the main housing structure, a master control board (electronic circuit system), a chip loading subsystem (including mechanical motion parts and current signal acquisition module), a fluidic subsystem (comprising the reagent storage system and liquid circulation system), and adapters and proprietary software (AxiLona EL Sys, model: AxiLona EL-100). The device automatically loads and ejects disposable microarray chips through a motor-driven mechanism to ensure smooth electrical connection with the instrument. Users interact with the device through a computer interface, with data exchanged via USB connection for the reading and analysis of electrochemical signals.

The production workflow of the AxiLona EL-100 involves assembly of subcomponents, debugging, appearance assembly, packaging and inspection. Key assembly processes include: (i) reagent bottlemounting frame assembly; (ii) reagent bottle assembly; and (iii) solenoid valve assembly. Each process incorporates defined quality control methods, such as torque screwdriver tightening to ensure sealing integrity and subsequent leak testing for verification. All assemblies are performed under a dual-personnel system, whereby one staff member operates and another verifies, with torque wrenches calibrated regularly and each screw traceable by tool number. Other subsystems are integrated to achieve automatic chip loading, liquid filling and drainage, signal detection, barcode entry, and chip ejection, thereby enabling a fully automated workflow with improved efficiency and accuracy.

Following assembly, specialized debugging software is used to configure and verify loading and ejection parameters, with manual cross-checking to ensure consistency and reliability. Each instrument undergoes a 1,440-minute aging test to confirm long-term durability before leaving the factory.

Production Process for Our Test Kits and Other Consumables

The following diagram illustrates the production process for our test kits and other consumables.



The following is a brief description of the key steps in our manufacturing process of test kits and other consumables.

- *Preparation of raw materials.* We procure raw materials from suppliers to satisfy subsequent production steps. Following receipt, we inspect these materials to ensure they meet our quality standards before storing them in appropriate warehouses. Upon retrieval from the warehouse, materials are temporarily stored in the production area until needed.

- *Solution preparation.* We add a certain volume of each component according to our product protocol and production operation manual to prepare a primary solution. We dilute the primary solution with diluent according to our product protocol and manufacturing manual to produce an intermediate reagent product.

- *Quality control sample preparation.* Our consumables include quality control samples, which are primarily positive control products and negative control products that are used as a reference to testing samples in order to ensure the operation accuracy of the testing process.

- *Formulation.* Upon completion of all preparation steps, we proceed with reagent formulation.

- *Semi-finished inspection and quality control.* Our quality control personnel monitor our entire production process. After the reagent preparation, our quality control personnel take samples of the intermediate reagent products for quality inspection.

- *Dispensing and Packaging.* We dispense the reagents of our consumables according to the requirements of our production operation manual for different categories of reagent kits. We package our consumables according to our production operation manual and relevant regulatory requirements.

- *Final inspection.* We conduct final inspection of our finished products.

PRODUCT WARRANTY, RETURN, RECALL AND EXCHANGES

For our commercialized products, our internal policy is to assume responsibility as required by law if the competent regulatory authorities find that our products are defective. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any such finding. We provide free repair services to customers within the specified warranty period of our products. In specific circumstances, following appropriate control procedures, we may authorize product returns or exchanges. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint or product return or exchange from customers. Neither had we experienced any product recall during the Track Record Period and up to the Latest Practicable Date.

SALES AND MARKETING

Sales of Our Products

During the Track Record Period, we mainly sell our products directly to our customers and we expect to rely on direct sales of our products in the foreseeable future. To expand our commercial footprint both within our domestic market and overseas market in the future and penetrate the in-hospital market in anticipation of our products' expanded clinical applications, we have started to engage distributors for the sales of our products. We believe collaboration with distributors enables us to access a broader customer base and will benefit our sales.

Direct Sales

In 2023, we have not generated any revenue from the sales of products. In 2024, a majority of our revenue from the sales of products were derived from direct sales. We have started and will continue to employ a series of effective and efficient measures to promote our direct sales to universities, hospitals and other academic institutions. For example, we have formulated strong connections with KOLs from a variety of universities and hospitals, who will help us promote our product sales through their professional background based on our products' satisfactory performance. The following is a summary of certain terms and conditions in our sales and purchase agreements involving the direct sales of our products:

- *Duration*. The contract is effective from the date of signing and remains valid until all obligations are fulfilled.

- *Sales and Purchase*. We will sell and deliver specified products at a fixed price provided in the agreement to the buyer.

- *Payment*. The buyer must pay the full amount as specified in the payment terms. We typically offer two payment options: 100% payment before shipment, or a certain percentage upfront and the remaining amount within specified months after shipment, subject to case-by-case negotiation.

- *Delivery*. We are responsible for delivering the products to the buyer's designated location within several working days, typically 60 working days, after receiving the payment and written shipping notice from the buyer. The buyer must cooperate in receiving the goods and sign the delivery documents upon receipt.

- *After-sales*. We provide ongoing technical support and maintenance services for the products.

- *Return.* Returns are only accepted for products with quality defects.

- *Confidentiality*. The buyer must keep all information related to the products confidential and use it only for the purposes specified in the contract.

- *Termination*. We reserve the right to terminate the contract without prior consent from the buyer and without further liability. In the event of termination by the buyer, a penalty as a certain percentage of the total purchase price is required.

Sales Through Distributors

We are in the process of establishing our distribution network and will expand the network after our products are approved for clinical use as well as we roll out new products. As of the Latest Practicable Date, we had seven distributors in China, and we currently do not have any sub-distributors. We generally operate a single-layer distribution system and do not allow distributors to engage sub-distributors within their designated geographic area, unless with our prior review and consent. Our arrangement of sales through distributors is consistent with common industry practices. According to CIC, it is customary in the medical device industry to rely on distributors for the sale of medical devices. Currently, we primarily engage distributors through fixed-term written distribution agreements. During the Track Record Period, to the best of our Directors' knowledge, none of our distributors had any past or present relationship (business or otherwise) with our Group, our shareholders, Directors, senior management or any of their respective associates.

We are highly selective in the distributors we engage. We seek to select distributors with valid licenses, well-established sales channels, historical performance, business operation status, wide coverage of hospitals, strong customer service and after sales service capabilities, a good credit profile, stable operation sites and sufficient financial capacity. We have established smooth communication channels with distributors which help us to gather necessary information to set reasonable sales targets for distributors and adopt appropriate sales and pricing strategies.

We recognize revenue from distributor sales when the products have been delivered, and titles have passed to the distributor upon its receipt. Please refer to "Financial Information — Material Accounting Policies and Significant Accounting Judgements and Estimates — Material Accounting Policies — Revenue Recognition" for more details of our revenue recognition policies.

Since receiving approval for commercial sale from the Jiangsu MPA for EL-100, we have actively collaborated with our distributors to promote the product and support early-stage commercialization. These efforts include joint participation in academic seminars, product roadshows, and trial evaluations aimed at demonstrating the clinical and research value of EL-100 to physicians and laboratory researchers. We have also conducted customer visits and participated in industry exhibitions to engage with potential end-users. In addition, we are working closely with key opinion leaders to enhance product credibility and market recognition. These promotional activities are designed to accelerate market adoption and lay the foundation for long-term growth.

As of the Latest Practicable Date, we had entered into a distribution agreement with a distributor in China, under which our products will be supplied at fixed prices and the distributor is responsible for distribution within its designated territory. Under this agreement, two units of AxiLona EL-100 have been sold. In addition to these agreements, we also engage certain distributors on a per-order basis, whereby products are supplied pursuant to individual purchase orders, with fixed pricing for each batch and contractual terms that are consistent with those of our direct sales agreements. The following is a summary of key terms of our fixed-term written agreements with distributors.

- *Duration.* The distribution agreements typically have a one-year term. The sales and purchase agreements are on an order-by-order basis.

- *Sales and purchase.* We will sell and deliver specified products at a fixed price provided in the agreement to distributor.

- *Payment.* The distributor must pay the full amount as specified in the payment terms. We require the distributor to pay 100% payment before shipment.

- *Delivery.* We shall deliver and install the products at our expenses, within a specific period after receiving the full payment (usually 30 days).

- *After-sales service.* We shall provide related ongoing technical support and maintenance services for a specific period after sale.

- *Return.* We do not accept product return except for products with quality defects, which is in line with market practice.

- *Confidentiality.* Distributor shall keep confidential any information relating to our products.

- *Geographic restrictions and exclusivity.* We grant our distributors exclusive rights to sell our designated products to their designated end-customers or end-customers within their designated territories. Our distributors are required to abide by geographic restrictions stipulated in the written agreements.

- *Sub-distributors.* Distributors are strictly prohibited from appointing sub-distributors within their authorized territories without our prior written consent. Where authorization is granted, distributors must submit sub-distributor profiles (including territorial scope, pricing terms, and performance metrics) and execute a tripartite agreement jointly with us.

- *Termination.* The agreement may be terminated by us when, among other things, the distributor fails to comply with relevant laws and regulations, fails to meet its target sales amount, or breaches any undertaking in the agreement and fails to remedy such breach within a specified period of time. Either party to the distribution agreement has the right to terminate the agreement with three months' notice.

Our Directors confirmed that there was no material breach of distribution agreements and sales and purchase agreements that caused the termination of such agreements during the Track Record Period.

Marketing

We primarily rely on our in-house team to formulate and execute marketing strategies. While we do harness the resources of a small number of distributors to promote our brand and products and to support our in-person events locally, our distributors take on more administrative and supportive roles in our overall marketing strategies. We also engage in extensive academic marketing activities with KOLs, physicians and researchers to promote our brand and establish a quality end-user base. Our academic marketing activities primarily include:

- establishing clinical collaboration with top-tier hospitals, pharmaceutical companies and research institutes,

- providing product education to potential and current customers, and

- participating in medical conferences and industry exhibitions to communicate with doctors, researchers and other industry players to keep abreast of the latest industry developments and clinical practices and to present our products and services and share our latest research and product development progress. For example, in March 2025, we attended the CACLP 2025 and organized a living streaming event to introduce our brand and products to potential customers.

We rely on KOLs to introduce and recommend our products to physicians and clinical researchers. KOLs have academic incentives in learning the latest molecular diagnostic and gene sequencing options available in China within their therapeutic areas and introducing cutting-edge technologies and products that they believe have clinical benefits to other physicians, all of which help maintain their reputation and standing within the broader medical community. In addition, we are also expanding our reach to other innovative areas to build reputation and recognition. For instance, we have established cooperative relationship with Nanjing customs in the field of identification of endangered species.

We have also established an active online presence through our social media accounts and our corporate websites at **www.axbio.cn/**. On these online channels, we provide extensive information about our technology platform, our superior products and solutions, and our competitive and technical advantages.

Pricing

We formulate and implement a reasonable pricing strategy for our marketed products to stay competitive and profitable. We primarily sold our products with prices in a fixed range during the Track Record Period. We take into account a number of factors in determining price for our products, which primarily include our R&D, production and marketing costs and expenses, the perceived value of products and services, our market share, and the competitive landscape.

We adopt a pricing strategy that combines cost-plus pricing with market competition analysis. The ex-factory price of EL-100 is determined based on a cost-plus approach, ensuring competitive pricing in the market. The end-user price is set to be more competitive compared to multiplex PCR detection technologies, taking into account market competition. Additionally, the pricing of medical devices is impacted by national reimbursement policies and tendering processes. Leveraging the cost advantages of EL-100, we are able to incorporate a buffer to address subsequent negotiations for potential price reductions with hospitals.

In addition, our pricing strategies may also be affected by the regulations and policies in the general medical device industry. As of the Latest Practicable Date, there was no pricing guidance or centralized procurement set by the PRC government on our products. If the PRC government issues pricing guidance for our products, the prices thereof may be negatively affected. For details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Commercialization of Our Product Candidates — Even if we are able to commercialize any products, the pricing of such products may be subject to downward changes, which may have a material adverse effect on our business, financial condition and results of operations." As of the Latest Practicable Date, the use of our products is not included in the medical insurance reimbursement list in China. We closely monitor new policies affecting the pricing of medical devices and their relevant services globally, and keep updating our pricing strategies to navigate in the evolving regulatory environment and cope with local policies and competition in different regions, intending to maintain the price levels of our products and maximize our overall sales.

OUR CUSTOMERS

We have a broad and diversified customer base. As of the Latest Practicable Date, we have sold our products to research institutes and hospitals in China and the U.S. Our customers generally have sound and stable financial conditions and pose low risk of default, which contributes to our healthy cash flow and our ability to operate in a volatile market. We have also earned strong loyalty among our customers.

During the Track Record Period, our customers were primarily research institutes and hospitals. We did not generate any revenue in 2023. In 2024 and the six months ended June 30, 2025, the aggregate sales to our five largest customers accounted for 98.1% and 100.0% of our total revenue, respectively, and sales to our largest customer accounted for 24.8% and 87.0% of our total revenue, respectively. The following table sets forth details of our five largest customers during the Track Record Period:

Five largest customers	Background	Products or services provided	Commencement of business relationship	Credit term	Revenue contribution *(USD in thousands)*	% of total revenue in same period
For the year ended December 31, 2024						
Customer A	A private company founded in 2018 in China that engages in the provision of medicine and healthcare-related services	EL-NGS gene sequencers	2024	Partial advance payment, balance paid after delivery and acceptance	119	24.8
Customer B	A private company founded in 2014 in China that engages in the provision of genetic testing services	EL-NGS gene sequencers	2024	Partial advance payment, balance paid after delivery and acceptance	118	24.6
Customer C	A private company founded in 2023 in Kazakhstan that engages in equipment distribution	Molecular diagnostic solutions	2023	Advance payment	91	19.0
Customer D	A public hospital founded in 1956	Molecular diagnostic solutions	2024	Partial payment after acceptance, balance paid later	72	15.0
Customer E	A leading comprehensive research university	EL-NGS gene sequencers	2023	Full payment upon delivery and acceptance	70	14.6
Total					**470**	**98.1**

Five largest customers	Background	Products or services provided	Commencement of business relationship	Credit term	Revenue Contribution *(USD in thousands)*	% of total revenue in same period
For the six months ended June 30, 2025						
Customer F	A private company founded in 2000 in China that engages in the provision of import and export services	EL-NGS gene sequencers	2024	Advance payment	463	87.0
Customer G	A private company founded in 2022 in Hong Kong that engages in the provision of import and export services	Molecular diagnostic solutions	2024	Advance payment	58	10.9
Customer H	A governmental public health institution in China, that is responsible for disease prevention and control, public health surveillance, and health promotion	Molecular diagnostic solutions	2024	Partial advance payment, balance paid after inspection	9	1.7
Customer I	A private company founded in 2012 in China that engages in the provision of comprehensive solutions for life science laboratories	Molecular diagnostic solutions	2025	Advance payment	1	0.2
Customer J	A private company founded in 2022 in China that engages in the provision of testing and healthcare-related services	Molecular diagnostic solutions	2025	Advance payment	1	0.2
Total					**532**	**100.0**

To the best knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital immediately following the completion of the **[REDACTED]** had an interest in any of our customers during the Track Record Period.

OUR SUPPLIERS AND RAW MATERIALS

Suppliers

During the Track Record Period, our suppliers mainly comprised of service providers across scientific research, facility operations, and professional technical support, and raw material suppliers. In 2023, 2024 and the six months ended June 30, 2025, purchases from our five largest suppliers in aggregate accounted for 28.4%, 33.0% and 17.9% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 6.9%, 10.8% and 5.9% of our total purchases for the same periods (including value added tax), respectively. Please see below a summary of the purchases from our five largest suppliers for the periods indicated.

Five largest suppliers	Principal business	Products or services purchased	Commencement of business relationship	Credit term	Purchase amount *(USD in thousands)*	% of total purchases in same period
For the year ended December 31, 2023						
Supplier B	A private company founded in 1999 in China that provides technical and other services to new high-tech enterprise	Site rental services	2022	Monthly payment	666	6.9
Supplier A	A renowned research institute founded in 2000 in China	Scientific research services	2017	Advance payment	639	6.6
Supplier F	A private company founded in 2017 in China that provides engineering construction and design services	Renovation Services	2022	Payment based on milestones	618	6.4
Supplier G	A private company founded in 2006 in China that provides engineering construction and design services	Renovation Services	2022	Payment based on milestones	474	4.9
Supplier H	A private company founded in 1993 in China that provides property management services	Property management services	2022	Advance payment	343	3.6
Total					**2,740**	**28.4**

Five largest suppliers	Principal business	Products or services purchased	Commencement of business relationship	Credit term	Purchase amount *(USD in thousands)*	% of total purchases in same period
For the year ended December 31, 2024						
Supplier A	A renowned research institute founded in 2000 in China	Scientific research services	2017	Advance payment	824	10.8
Supplier B	A private company founded in 1999 in China that provides technical and other services to new high-tech enterprise	Site rental services	2022	Monthly payment	601	7.8
Supplier C	A private company founded in 1993 in China that provides corporate and enterprise management services	Labor dispatching services	2022	Advance payment	411	5.4
Supplier D	A famous law firm in the U.S.	Legal services	2018	Advance payment	407	5.3
Supplier E	A private company founded in 2020 in China that engages in technology research and development and equipment sales	Equipment	2024	Advance payment	281	3.7
Total					**2,524**	**33.0**

Five largest suppliers	Principal business	Products or services purchased	Commencement of business relationship	Credit term	Purchase amount *(USD in thousands)*	% of total purchases in same period
For the six months ended June 30, 2025						
Supplier B	A private company founded in 1999 in China that provides technical and other services to new high-tech enterprise	Site rental services	2022	Monthly payment	301	5.9
Supplier D	A famous law firm in the U.S.	Legal services	2018	Payment upon invoice	261	5.1
Supplier C	A private company founded in 1993 in China that provides corporate and enterprise management services	Labor dispatching services	2022	Advance payment	137	2.7
Supplier I	A private company founded in 1980 in the U.S. that engages in the provision of semiconductor manufacturing services	Wafers	2023	Advance payment	109	2.1
Supplier J	A private company founded in 1992 in China that engages in the provision of site rental services	Site rental services	2021	Advance payment by quarter	105	2.1
Total					**913**	**17.9**

To the best knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital immediately following the completion of the **[REDACTED]** had an interest in any of our suppliers during the Track Record Period.

Overlapping of Customers and Suppliers

Customer E was one of our five largest customers in 2024, and also a supplier of ours in both 2023 and 2024. We engaged Customer E to provide R&D services for us, and Customer E purchased our EL-NGS gene sequencers during the Track Record Period. The transaction amount of our purchase from Customer E as a percentage of our total purchases was 0.5% and 2.6% in 2023 and 2024, respectively. In 2024, the revenue generated from Customer E was US$70.0 thousand, while the costs of sales and gross profit related to Customer E were US$13.0 thousand and US$57.0 thousand, respectively. These amounts corresponded to 14.6%, 7.4% and 18.7% of our total revenue, costs of sales, and gross profit for the year, respectively.

The relationship with Customer E is an example of a symbiotic industry-academia collaboration. We engaged the university to leverage its high-end R&D capabilities and access its leading research expertise. We commissioned the university to provide specialized R&D services to us. Concurrently, the university purchased our EL-NGS gene sequencers. As a leading academic institution, it requires equipment for its own research projects and educational purposes. We expect that the magnitude of such overlap will not increase with the evolvement of our business operations.

Negotiations of the terms of our sales to and purchases from Customer E were conducted on an individual basis, and the sales and purchases were neither inter-connected nor inter-conditioned with each other. Our Directors confirm that all of our sales to and purchases from Customer E were conducted in the ordinary course of business under normal commercial terms and on arm's length basis. Our Directors confirm that, saved as disclosed above, none of our major suppliers was our customers, or *vice versa*, during the Track Record Period.

Raw Materials

For our products and product candidates, we primarily use raw materials including (i) printed circuit board assembly, pumps, wafers, valves, plastic parts, and metal processing components for our products, and (ii) enzymes, probes, primers, common chemical reagents, and screw-cap tubes for test kits. Among these raw materials, we in-house produce certain enzymes, probes, chemical reagents. We may expand our own production lines to enable manufacturing of other certain raw materials. We select our raw material suppliers based on a number of factors, including the quality of raw materials, after-sales service and price. We use reputable suppliers from China, Europe and other countries. Based on the current market conditions, we intend to maintain stable working relationships with our major suppliers of raw materials. However, we cannot assure that we will maintain our working relationships with our major suppliers on similar terms, if at all. Although we maintain a list of backup suppliers if any supplier fails to timely deliver raw materials, we are still subject to risks associated with shortage of raw materials. For details, see "Risk Factors — Risks Relating to Our Business — Risks Relating to the Manufacturing of Our Product Candidates — We depend on third-party suppliers to supply raw materials to be used in manufacturing our products. If these suppliers can no longer provide satisfactory products with high quality to us on commercially reasonable terms, our business, financial condition and results of operations could be adversely affected" in this document. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulties in procuring our major raw materials and had not experienced significant fluctuations in the prices of our supplies. To the best knowledge of our Directors, there had been no material breach of our procurement agreements with our suppliers during the Track Record Period.

INVENTORY MANAGEMENT

Our inventory mainly consists of raw materials and consumables used on our proprietary instruments, as well as finished goods. We regularly monitor our inventories and endeavor to keep an optimal inventory level in line with the expected usages in the near term. We operate warehouses and have established an inventory management system

to monitor each stage of the warehousing process. Warehouse personnel are responsible for the inspection, storage and distribution of raw materials. Our Directors confirmed that our inventory control system and policies had been effective and we did not experience any material shortage in supply or overstock of inventories during the Track Record Period and up to the Latest Practicable Date.

QUALITY CONTROL

The quality, safety and reliability of our products are vital to our continued success. Our quality control and regulatory team is involved in every aspect of our daily operations to ensure the quality control of our products. We have established an internal control protocol for the design and development of medical devices with reference to various domestic and international risk management standards, including GMP, GB/T42061-2022 and GB/T42062-2022 idt ISO14971:2019. We provide trainings to relevant employees to ensure that they are able to correctly and effectively implement our quality control system. Our quality control procedures in the production process primarily consist of the following:

- *Raw material control and inspection.* We conduct meticulous due diligence on our suppliers and only purchase our raw materials from suppliers whose qualifications satisfy our internal supply management policies. We also inspect samples from each batch of raw materials to help ensure there are no quality or other issues;

- *Process control.* We plan the production process based on the technologies adopted by each product type and monitor the entire production process, particularly certain key steps of the production process. Each semi-finished product is required to go through the QC inspection and QA confirmation process to be used for the next stage manufacturing step;

- *Product inspection.* We compile our product inspection manual based on our product specifications, and inspect our products in accordance with our product inspection manual, including testing the capability and measurement of our products, verifying the product labels and manuals as well as confirming that the products are properly packaged; and

- *Product release.* During the production process, all records, procedures, methodologies, and inspection logs are meticulously reviewed to ensure they align with product specifications and quality standards. Upon verification, our products are granted entry into the warehouse, accompanied by the release document and a certificate of conformity.

We had complied with all of our quality qualification requirements in material respects up to the Latest Practicable Date. During the Track Record Period and up to the Latest Practicable Date, we had not received any material complaints about product quality and our products had not been subject to any material claim, litigation or investigation.

INTELLECTUAL PROPERTY RIGHTS

We have built an extensive intellectual property portfolio in China and overseas to protect our technologies, inventions and know-how. As of the Latest Practicable Date, we had 53 issued patents and 41 patent applications in China, 13 issued patents and 13 patent applications the U.S. and other jurisdictions. We also have four layout-design of integrated circuits registered in China. Specifically, in relation to our Core Product, AxiLona EL-100, we had five issued patents and nine patent applications as of the Latest Practicable Date. We believe there is no material legal impediment to obtain the approvals for these pending patents. The following table sets forth material patents relating to our Core Product and Key Product as of Latest Practicable Date.

Related Product	Title of Patent	Jurisdiction	Patent Holder	Date of grant
AxiLona EL-100	A liquid system and a nucleic acid testing device (一種液路系統及核酸檢測設備)	PRC	Anxuyuan Wuxi	July 25, 2023
AxiLona EL-100	A chip for calibrating a testing device (一種校正檢測儀器的芯片)	PRC	Anxuyuan Wuxi	July 25, 2023
AxiLona EL-100	Microfluidic chips and nucleic acid testing devices (微流控芯片及核酸檢測設備)	PRC	Anxuyuan Wuxi	August 18, 2023
AxiLona EL-100	Systems and methods for assessing a target molecule	Japan	Axbio US	January 14, 2025
AxiLona AXP-100	Methods for processing a nucleic acid sample and compositions thereof	U.S.	Axbio US	March 18, 2025
AxiLona AXP-100	Methods, systems, and compositions for nucleic acid sequencing	U.S.	Axbio US	February 18, 2025
AxiLona AXP-100	Methods, systems, and compositions for nucleic acid sequencing	U.S.	Axbio US	March 14, 2023
AxiLona AXP-100	Biomolecule diagnostic systems	U.S.	Axbio US	November 1, 2022
AxiLona AXP-100	Sequencing reagents (測序試劑)	PRC	Anxuyuan Shenzhen and Anxuyuan Wuxi	November 8, 2022
AxiLona AXP-100	Integrated circuits for analyzing biological systems	U.S.	Axbio US	March 23, 2021
AxiLona AXP-100	Apparatus and methods for continuous diagnostics of macromolecules	U.S.	Axbio US	February 9, 2021
AxiLona AXP-100	Devices and methods for measuring the properties of macromolecules	U.S.	Axbio US	December 17, 2019
AxiLona AXP-100	Gene sequencing apparatus and gene sequencing methods (基因測序裝置和基因測序方法)	PRC	Anxuyuan Shenzhen	June 27, 2023

Related Product	Title of Patent	Jurisdiction	Patent Holder	Date of grant
AxiLona AXP-100	Preparation method of branch-like macromolecule-modified nucleotides (樹杈狀大分子修飾的核苷酸的製備方法)	PRC	Anxuyuan Shenzhen	October 21, 2022
AxiLona AXP-100	Microfluidics devices and gene sequencer (微流體裝置及基因測序儀)	PRC	Anxuyuan Shenzhen	June 11, 2024

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned, licensed, or issued patents or any such patents that may be issued in the future will be commercially useful in protecting our core product and pipeline products and methods of manufacturing the same.

Based on the freedom to operate ("**FTO**") analysis of certain core technologies of our Core Product and Key Product, we were not aware of any issued patents that may affect our rights to conduct research and development or commercialization of our Core Product and Key Product in China and the U.S. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to determine whether any existing patents cover a company's product, and whether that product would infringe any existing patents. However, we cannot provide any assurance that all relevant third party patents were identified or that conflicting patents will not be issued in the future.

We rely, in some circumstances, on trade secrets or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering confidentiality arrangements with consultants, advisors, and other third parties. We have entered into labor contract with intellectual property assignments and confidentiality provisions with all of our employees, pursuant to which intellectual property conceived and developed during their employment belongs to us, and they have waived all relevant rights or claims to such intellectual property. We have also entered into non-compete agreements with key employees. We also have established an internal policy governing the confidentiality of all company information.

However, the confidentiality arrangements may not provide enough protection of our trade secrets or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to

or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to protect our trade secrets and proprietary information sufficiently. For details, please refer to "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — If we are unable to protect the confidentiality of our trade secrets, our business and 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."

As of the Latest Practicable Date, we had registered trademarks for our Company and our corporate logo in China and are seeking trademark protection for our Company and our corporate logo in the countries where available and appropriate.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings regarding intellectual property rights infringement claims against us or initiated by us. However, there are risks if we fail to protect our intellectual property rights in the future. For details, please refer to "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights."

DATA PRIVACY AND PROTECTION

We are subject to stringent data privacy and protection laws and have implemented comprehensive policies and internal controls to govern our collection, use, and handling of data. Our handling of sensitive data for current operations limits to personal health data including diagnostic results of clinical trial subjects. We routinely receive, collect, generate, store, process, transmit, and secure sensitive data, which is central to our clinical trials, and the provision of our products and services. This data is currently primarily collected from clinical trial subjects. Besides, we do not use any personal data for training AI for current products and services. Accordingly, we are subject to relevant local, national, and international data protection and privacy laws and regulations in the jurisdictions where we operate, including the PRC.

Our data management lifecycle is designed to ensure compliance with applicable laws and respect for user privacy from collection to deletion.

- ***Data Collection and Use***. We indirectly handle and are exposed to certain data, including desensitized personal and health information generated from our clinical trails. Such data are collected by hospitals or CROs from enrolled subjects, and are shared with us only to the necessary extent. The information primarily includes initials, sex, age, test result, diagnostic information. This data is essential for conducting our clinical trials, for the research and development of our product candidates, and for providing and improving our services. We also collect contact information and comments from viewers of our official websites for connection with potential customers. We do not collect or use any data generated during the provision of product or services by customers, which is solely under customers' control and cannot be accessed. Besides, we only use data generated during internal device tests and detection, or publicly available data for training of AI functions. We do not

use any personal data for training purpose. We ensure the compliance of all acquisition of training data by abiding by the website terms of use and applying our internal technical and management protection measures.

- ***User Consent***. We do not collect or use any data without obtaining prior consent. For clinical trials, we obtain explicit written informed consent from every trial subject before their enrollment through informed consent letter prepared by the sites of the clinical trial. The scope of consent is clearly defined, specifying the purposes for which the data may be used, including for the specific clinical trial and potentially for future scientific research, subject to applicable laws. Furthermore, for website viewers, our website privacy policies detail the processing purposes, scope and data retention period, after which the data is scheduled for secure deletion or anonymization. Our privacy policies stipulate that the data storage time should be minimized. Data retention period shall not be longer than the consented retention period or any retention period as stipulated by law. Data is scheduled for secure deletion or anonymization after the retention period or upon request by the data provider.

- ***Data Storage, Sharing, and Deletion***. Data is stored on secure, encrypted servers with strict access controls. We have established protocols for the secure deletion and destruction of data once it is no longer required for the authorized purpose or upon the expiration of the retention period.

Regarding cross-border data transfer, our current overseas operations only involve sharing R&D progress, product specifications, and performance study reports with overseas entities for the purpose of synchronizing R&D initiatives and providing technical support. To clarify, our existing activities do not entail any cross-border transfer of personal information of trial subjects or human genetic resources. In light of our potential expansion into overseas markets, including future clinical trials in the United States, we are committed to full compliance with applicable laws and regulations governing cross-border data transfer, cybersecurity, and data security, including the relevant provisions stipulated by the Cyberspace Administration of China and the laws of the recipient jurisdiction.

We have implemented a comprehensive system of internal controls and management policies to ensure the privacy and security of data, prevent data leakage, and ensure proper authorization for data usage across our business, including for AI training. These measures are enforced to ensure legal and regulatory compliance. Key measures include:

- ***Data Governance and Management***. We have established standard operating procedures (SOPs) for data management throughout its lifecycle, including data management, data validation, and secure handling, particularly for clinical data.

- ***Technical Security***. We have implemented technical safeguards such as data encryption for data at rest and in transit, firewalls, intrusion detection systems, and strict access control mechanisms to ensure that data is only accessible by authorized personnel on a "need-to-know" basis.

- ***Authorization and Usage Control***. We have specific protocols that govern the authorization and usage of data for AI model training, ensuring that only properly de-identified data is used and that the usage aligns with the scope of user consent.

- ***Employee Training and Confidentiality***. All our employees are required to enter into confidentiality agreements and receive mandatory, regular training on data protection regulations, our internal privacy policies, and security best practices.

- ***Incident Response***. We have established an emergency response plan to promptly address any potential data security incidents or breaches.

During the Track Record Period and up to the Latest Practicable Date, based on confirmation from our PRC Legal Advisor, we have complied with all applicable PRC laws and regulations related to data security and privacy in all material aspects. We have not been subject to any material administrative penalties or been the target of any material regulatory inquiries in relation to data privacy and protection.

For further details regarding the risks associated with data privacy and protection, please see "Risk Factors — Risks Relating to Our Business — We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security."

COMPETITION

We operate in a rapidly changing market, resulting from technological advances and scientific discoveries. Principal competitive factors important to our success include superior performance of our molecular diagnostic and gene sequencing products, strong multidisciplinary and proprietary technology capabilities, established brand awareness and end-user recognition, effective sales channels, a stable supply chain and the ability to navigate and comply with stringent regulation. For additional details regarding the competitive landscape of the industry in which we operate, please refer to "Industry Overview." We believe we have established strong competitive advantages with our highly synergistic and comprehensive portfolio and R&D-driven innovation, which we expect to enable us to sustain our market position and capture future opportunities. We strive to rapidly advance our product candidates into commercialization and receiving approval to solidify our first-mover advantage amongst other players in the industry with respect to clinical application of molecular diagnostic and gene sequencing, supported by developing test kits with regulatory approval or through other pathways.

AWARDS AND RECOGNITION

The following table sets out a summary of the major awards and recognition we have received as of the Latest Practicable Date.

Year	Award or Recognition	Issuing Authority
2025	Best Team Award at "Kechuang • Lake Liuye" Synthetic Biology Innovation and Entrepreneurship Competition	Department of Commerce of Hunan Province and The People's Government of Beijing Municipality
2024	2024 Future Healthcare 100 Strong: China Innovative Medical Devices and Intelligent Manufacturing TOP 100	VB100, Artery Net, Eggshell Research Institute
2024	2024 Medical Device Industry Top 100 Emerging Enterprises Innovation Index and 2024 Medical Device Industry Innovation Index in In Vitro Diagnostics (IVD) Sector	National Innovation Center for Advanced Medical Devices
2024	Advancement to the Semi-Finals of the 16th China (Shenzhen) Innovation and Entrepreneurship Competition	Organizing Committee of China (Shenzhen) Innovation and Entrepreneurship Competition
2023	2023 Greater Bay Area Enterprise Innovation Power List: Future Creator Star List	Shenzhen Industrial Federation
2023	2023 VentureBeat 100 Future Unicorn List	VentureBeat
2023	China Innovative Medical Device TOP 100	VB100, Artery Net, Eggshell Research Institute
2022	2022 First Batch of National "High-Tech Enterprises"	National High-Tech Enterprise Recognition Management Working Leadership Group Office
2022	2022 China Top 100 Emerging Enterprises in High-Performance Medical Devices	National Innovation Center for Advanced Medical Devices

Year	Award or Recognition	Issuing Authority
2021	Beyond Awards	BEYOND Expo
2021	4th Greater Bay Area Biotechnology Innovation Enterprise 50 Strong: Pioneer Enterprise	China Innovation Research Institute, Guangdong Medical Valley
2018	Nanshan Leading Team Program	Shenzhen Nanshan District Science and Technology Innovation Bureau

EMPLOYEES

As of the Latest Practicable Date, we employed 119 full-time employees, the majority of whom were based in China. The following table sets forth the number of our full-time employees by function as of the Latest Practicable Date.

Function	Number	% of Total
R&D	75	63.0
Manufacturing and quality control	19	16.0
Management and administrative affairs	16	13.4
Sales and marketing	9	7.6
Total	**119**	**100.0**

We enter into an employment contract with each employee covering matters including salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause, and grounds for termination, among others. We have entered into labor contract with intellectual property assignments and confidentiality provisions with all of our employees. We have also entered into non-compete agreements with key employees.

To maintain our workforce's quality, knowledge, and skill levels, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional, or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses, and share-based payment to our employees, particularly our key employees.

During the Track Record Period, we did not pay social insurance and housing provident funds in full for some of our employees in strict compliance with relevant laws and regulations. We have made full provisions in respect of the outstanding amount of the social insurance and housing provident fund contributions. In 2023, 2024 and the six

months ended June 30, 2025, our shortfall of contribution to social insurance and housing provident funds amounted to US$739.0 thousand, US$524.0 thousand and US$249.0 thousand, respectively.

We have taken the following rectification measures to prevent future occurrence of such non-compliance: (i) we plan to strengthen legal compliance training to our employees to increase their awareness of the relevant PRC laws and regulations and encourage their cooperation in making payments for social insurance and housing provident funds; (ii) we have implemented and distributed to our employees an internal control policy with respect to social insurance and housing provident fund contributions in compliance with relevant PRC laws and regulations; and (iii) we plan to regularly consult external counsel to assess whether we are at risk of non-compliance with the relevant laws and regulations.

As advised by our PRC Legal Advisor, under the relevant PRC laws and regulations, an employer that fails to pay social insurance contributions in full and on time may be ordered by the applicable authority to make the payment of the outstanding contributions within a stipulated deadline. A late payment fee of 0.05% of the outstanding amount per day may also be imposed from the date of default. We estimate that in the event that we are ordered to make up for the social insurance outstanding contributions during the Track Record Period, the maximum late payment fee would be approximately RMB1.1 million as of June 30, 2025. If the employer still fails to rectify the failure to make social insurance contributions within the stipulated deadline, it may be subject to a fine ranging from one to three times of the amount overdue. In addition, an employer that has failed to pay the housing provident fund on time or underpaid the housing provident fund in violation of relevant regulations, may be ordered to make the payment within a stipulated deadline. If the employer still fails to make the payment within the stipulated deadline, the competent authorities may apply to the court for compulsory enforcement.

As advised by our PRC Legal Advisor, and in light of the relevant facts outlined above, if we promptly pay the historical outstanding amounts within the stipulated timeframe as required by the competent authority, the likelihood that we are subject to late payment fees and any material penalties due to our failure to provide full social insurance and housing provident funds contributions for our employees is remote. As of the Latest Practicable Date, no competent government authorities had imposed fine or penalty to us with respect to this non-compliance incident.

According to the Interpretation II of the Supreme People's Court of Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) enacted by the Supreme People' Court on July 31, 2025 and implemented on September 1, 2025. Where an employer and an employee enter into a written or verbal agreement that social insurance premiums need not be paid by both parties, the people's court shall not support this arrangement and shall determine that the agreement is invalid. Accordingly, when an employer fails to pay social insurance premiums even as previously agreed between the employer and an employee, upon the employee's termination of the employment contract, the employer shall make up the unpaid social insurance premiums and pay economic compensation to the employee in accordance with the provisions of the Labor Law.

According to the confirmation of our Group and Directors, as of the Latest Practicable Date, (i) no employee has raised any disputes with our Group regarding social security and housing provident fund matters, and our Group has not received any litigation documents related to labor disputes (especially those related to social security and housing provident fund contributions); and (ii) even if relevant labor disputes arise, they only involve economic compensation, the economic compensation amount does not have a significant financial impact on our Group's business operations. Based on legal provisions and confirmation from our Group and our Group's Directors, our PRC Legal Advisor is of the view that the risk of the formal implementation of the aforementioned judicial interpretation has the material adverse impact on our Group is remote.

We consider our relations with our employees to be good. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business.

PROPERTIES

As of the Latest Practicable Date, we leased five properties in Shenzhen, Wuxi, and Tianjin in China, with a gross floor area of approximately 7,972.33 sq.m., and two properties in the U.S., with a gross floor area of approximately 10,400 sq. ft. We believe our current facilities are sufficient to meet our near-term needs, and we can obtain additional space on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table sets forth a summary of the properties leased by us of the Latest Practicable Date.

No.	Type of Property	Location	Gross Floor Area	Lease Term
1	Premises	Shenzhen	1,557.42 sq. m.	2025.10-2026.10
2	Premises	Shenzhen	1,557.41 sq. m.	2025.10-2026.10
3	Premises	Wuxi	1,506 sq. m.	2023.01-2027.12
4	Premises	Wuxi	2,620 sq. m.	2022.07-2027.06
5	Premises	Tianjin	731.5 sq. m.	2025.01-2025.12
6	Premises	U.S.	4,000 sq. ft.	2023.05-2026.05
7	Premises	U.S.	6,400 sq. ft.	2024.08-2026.05

Pursuant to the applicable PRC laws and regulations, property lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, we had not completed the relevant property leasing registrations for one lease agreement. For details of the risk associated with the unregistered lease agreements, please refer to "Risk Factors — Risks Relating to Doing Business in the Jurisdiction Where We Mainly Operate — One lease agreement of our leased properties has not been registered with the relevant PRC government authorities as required by PRC law, which may expose us to potential fines." According to our PRC Legal Advisor, the failure to complete such registration process does not affect the validity of the relevant property lease agreements, and a maximum

penalty of RMB10,000 may be imposed for the non-registration of each lease agreement. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising from the non-registration of our lease agreement, and had not experienced any dispute arising out of, or in relation to, our leased properties.

INSURANCE

Our principal insurance policies cover property and general liability. We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and aligns with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims. For risks relating to our insurance coverage, please refer to "Risk Factors — Risks Relating to Our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources."

LICENSES, PERMITS AND APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, permits, and approvals from relevant authorities that are material to our operations, and such licenses, permits, and approvals all remain in full effect. For more details regarding the PRC and foreign laws and regulations to which we are subject, please refer to "Regulatory Overview."

The table below sets forth the relevant details of the material licenses we hold for our operation as of the Latest Practicable Date.

License/Permit	License/ Permit No.	Entity	Grant Date	Authority	Validity Period
Medical Device Production License (醫療器械生產許可證)	20250068	Anxuyuan Wuxi	April 2025	Jiangsu MPA	April 11, 2025 to April 10, 2030
Class I Medical Device Production Record Filing Certificate (第一類醫療器械生產備案憑證)	20230018	Anxuyuan Wuxi	August 2023	Wuxi Municipal Bureau of Administrative Examination and Approval	Long term
Medical Device Registration Certification (醫療器械註冊證)	20252220593	Anxuyuan Wuxi	April 2025	Jiangsu MPA	April 7, 2025 to April 6, 2030
Class I IVD Reagent Record Filing (第一類體外診斷試劑備案信息表)	20230086, 20230087, 20230088	Anxuyuan Wuxi	July 2023	Wuxi Municipal Bureau of Administrative Examination and Approval	Long term
Class I Medical Device Record Filing Certificate (第一類醫療器械備案憑證)	20190490	Anxuyuan Shenzhen	July 2019	Shenzhen Municipal Food and Drug Administration	Long term

License/Permit	License/ Permit No.	Entity	Grant Date	Authority	Validity Period
Class II Medical Device Distribution Record Filing Certificate (第二類醫療器械經營備案憑證)	20230580	Anxuyuan Medical Technology	March 2025	Wuxi Municipal Bureau of Date Administration	Long term
Medical Device Distribution License (醫療器械經營許可證)	20250043	Anxuyuan Medical Technology	March 2025	Wuxi Municipal Bureau of Data Administration	March 11, 2025 to March 10, 2030

We intend to apply for renewal of the above key licenses prior to their respective expiry dates. The successful renewal of our existing licenses, permits, and approvals will be subject to our fulfillment of relevant requirements. Our Directors are not aware of any reason that would cause or lead to the non-renewal of the licenses, permits, and approvals. Our PRC Legal Advisor confirmed that as of the Latest Practicable Date, there was no material legal impediment for us to renew the licenses, permits, and approvals as long as we comply with the relevant legal requirements.

IMPACT OF COVID-19

The COVID-19 pandemic did not have any material adverse impact on our operations or financial performance during the Track Record Period and up to the Latest Practicable Date. During the Track Record Period, we were primarily engaged in internal research and development activities, and our key raw materials were largely under our own control and supply. As such, our business operations remained stable and uninterrupted. Our Directors are of the view that the COVID-19 pandemic did not materially affect our business, results of operations or financial condition during the Track Record Period and up to the Latest Practicable Date. To the best knowledge of the Company, we did not observe any significant intensification of market competition in our addressable markets as a result of the pandemic.

IMPACT OF GEOPOLITICAL TENSIONS

On March 29, 2024, members of the U.S. House Select Committee on the Strategic Competition Between the United States and the Chinese Communist Party submitted a letter to the U.S. Department of Defense proposing the inclusion of certain biotechnology companies, including our Company, in the "List of Entities Identified as Chinese Military Companies" under Section 1260H of the National Defense Authorization Act for Fiscal Year 2021 (the "1260H CMC List"). Following this proposal, we promptly conducted an internal assessment and engaged in communications with the U.S. Department of Defense. As a result of these communications, the Department confirmed in May 2024 that we were not included in the published list. Furthermore, the subsequent list released on January 7, 2025, also did not include our Company. For details, see "Risk Factors — Risks Relating To Extensive Government Regulations — All material aspects of the research, development and commercialization of our products are heavily regulated. Any failure to comply with relevant laws and regulations may adversely affect our business, financial condition, results of operations and prospects." As of the Latest Practicable Date, we have

not been included in the 1260H CMC List and have not engaged in further consultations with the U.S. Department of Defense. Based on the foregoing, our Directors are of the view that the proposal has not had, and is not expected to have, any material adverse impact on our business operations, financial condition, or prospects. Based on the independent due diligence work conducted by the Joint Sponsors, nothing has come the attention of the Joint Sponsors that would cause doubt on the reasonbleness of the Directors' view above.

As of the Latest Practicable Date, the U.S. government has imposed cumulative tariffs on imports from China of up to 245%, while China has imposed retaliatory tariffs of up to 125% on imports from the United States. Such measures and other potential trade restrictions or sanctions may result in delays or disruptions to our customers', suppliers', and research partners' ability to acquire or use technologies, systems, products, or materials critical to their operations, and could adversely affect the global regulatory and political environment. For risks relating to international trade and geopolitical tensions, please refer to the section headed "Risk Factors — Risks Relating to Our Operations — Changes in U.S. and international trade policies, particularly with regard to China, may cause disruptions to our clinical development, manufacturing processes and other aspects of our business and operations."

Our commercialization efforts in the United States remain at an early stage and are not yet significant. We expect to sell products originating from China to the U.S. market as part of our global distribution strategy. Recent rounds of U.S.-China tariff negotiations have led to a substantial reduction in reciprocal tariffs. According to CIC, advanced medical devices generally exhibit low sensitivity to tariff fluctuations in downstream demand, which is consistent with the market observations.

To mitigate potential geopolitical risks, we have implemented a number of structural and operational measures. The Company has structured its organization and defined its intellectual property (IP) ownership to support a global operations model centered on localized research and development capabilities and localized manufacturing of key components. This approach enables parallel production capabilities in our two major markets, China and the United States, providing enhanced operational flexibility as needed. In addition, we have diversified our supply chain to reduce reliance on any single jurisdiction or supplier. We also maintain full ownership of all material intellectual property related to our product design and manufacturing processes, and do not rely on restrictive licensing arrangements. This enables us to retain control over our proprietary technologies and adapt flexibly to evolving regulatory environments.

We have not made any material adjustments to our allocation of resources, including technologies, manpower, sales and marketing efforts, production facilities, or R&D centers, in response to geopolitical developments. Our existing infrastructure supports flexible deployment across jurisdictions, and we continue to monitor global developments to ensure strategic agility.

Taking into account the factors above, our Directors are of the view that there has been no material direct or indirect impact of trade restrictions or tariffs on our operations, commercialization plans, or relationships with customers, suppliers, or government authorities as of the Latest Practicable Date, and nothing has come to the attention of the Joint Sponsors that would cause them to disagree with the Directors' view above.

HEALTH, SAFETY, SOCIAL AND ENVIRONMENTAL MATTERS

We acknowledge our environment protection and social responsibilities and are aware of the environmental, energy, climate-related and workplace safety issues that may impact our Group's business operations. Our Board has overall responsibility for (i) overseeing and determining our Group's environmental, social, and climate-related risks and opportunities that impact our Group, (ii) establishing ESG related targets of our Group, (iii) adopting the ESG related policies, and (iv) reviewing our Group's performance in ESG matters. We have implemented company-wide environmental, health and safety ("**EHS**") policies and standard operating procedures in relation to work safety, environmental protection, fire safety, emergency response and occupational health. During the Track Record Period and up to the Latest Practicable Date, we did not incur a material cost of compliance with relevant environmental protection laws and regulations. We are committed to complying with environmental, social and governance ("**ESG**") reporting requirements upon [**REDACTED**].

During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material respects and had not been subject to any material claim or penalty in relation to health, safety, social and environmental protection, or been involved in any significant workplace accident or fatality, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations during the same period.

Environmental Protection

We strive to operate our facilities in a manner that protects the environment. We do not operate in a highly polluting industry, but the R&D and manufacturing process of our instruments, test kits and product candidates for clinical trials and research involves the use of hazardous chemicals, flammable and toxic materials, and may exhaust gas and generate liquid waste, solid waste, and other hazardous waste. In 2023, 2024 and six months ended June 30, 2025, we incurred costs for treating hazardous waste of RMB86.4 thousand, RMB92.8 thousand and RMB32.6 thousand, respectively. To ensure compliance with national, industrial, and local environmental standards, laws, regulations, and policies, we have implemented internal policies for environmental risk prevention. These policies include stringent guidelines of procedures for operating in our laboratory and manufacturing facilities in relation to environmental protection.

Our main environmental treatment procedures are as follows:

- ***Liquid waste management***. Liquid waste, generated from processes such as equipment cleaning and laboratory operations, is systematically collected and stored at our internal facilities. This waste is then periodically transferred to a certified third-party company specializing in professional treatment and disposal, ensuring full compliance with all environmental regulations.

- ***Solid waste and other hazardous waste treatment***. General solid waste is collected and disposed of by sanitation services. Hazardous waste is collected and entrusted to qualified third-party units for disposal.

- ***Air pollution treatment***. Air emissions from our laboratory and manufacturing facilities undergo treatment, such as activated carbon adsorption, before being discharged.

Resource Consumption and Emissions

We conduct environmental impact assessments to monitor emission levels. We use a range of metrics to evaluate the impact of environmental risks. The following table sets forth, in a tabular format, our actual energy consumption, emissions, and wastes (and their intensity) produced during the Track Record Period in China.

	For the year ended December 31,		For the six months ended June 30,
	2023	**2024**	**2025**
Energy consumption			
Electricity *(MWh)*			
– Total amount	1,049	1,019	399.1
– Intensity* *(MWh/RMB million)*	68.6	89.3	88.7
Water *(tons)*			
– Total amount	3,337	2,563	1,227
– Intensity* *(tons/RMB million)*	218.1	224.8	272.7
Waste			
Liquid waste *(tons)*			
– Total amount	16.6	13.9	6
– Intensity* *(tons/RMB million)*	1.1	1.2	1.3
Solid waste *(tons)*			
– Total amount	8.3	5.3	2
– Intensity* *(tons/RMB million)*	0.5	0.5	0.4

Note:

* Calculated as the total amount of resource consumption or emission divided by the R&D expense of the respective year.

Our electricity consumption in China from 2023 to 2024 remained relatively stable. The decreases in the total amounts of water consumption, liquid waste, and solid waste from 2023 to 2024 were a direct result of our enhanced resource management efforts and water conservation initiatives implemented during the year.

In 2023, 2024 and six months ended June 30, 2025, our quantified emissions from energy consumption in China were 584.3, 567.1 and 222.2 tonnes of CO_2, respectively. These figures were calculated based on our total electricity usage multiplied by China's national average grid emission factor, sourced from the National Greenhouse Gas Emission Factor Database. During the same periods, our quantified transportation emissions were 157.0 tonnes of CO_2 in 2023, 128.3 tonnes of CO_2 in 2024 and 59.6 tonnes of CO_2 in the six months ended June 30, 2025. This category includes employee commuting, with emissions estimated based on an internal employee survey of travel modes and distances, and business travel, with emissions calculated using corporate travel records. The emission factors for both commuting and business travel were primarily sourced from the China Products LCI (Life Cycle Inventory) Greenhouse Gas Emission Factor Database. Our CO_2 emissions from energy consumption in China from 2023 to 2024 remained relatively stable. The decrease in transportation emissions in China was primarily a result of a decrease in the number of our employees.

During the Track Record Period and up to the Latest Practicable Date, we had not received any fines or penalties associated with the breach of any environmental laws or regulations. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

ESG Goals, Targets and Policies

Goals and Targets

The Board will set targets for material key performance indicators ("**KPIs**") in accordance with the disclosure requirements under Appendix C2 to the Listing Rules. When setting the targets for environment-related KPIs, we will take into account our consumption and emission levels during the Track Record Period and consider our future business expansion in a comprehensive and prudent manner, with a view to striking a balance between business growth and environmental protection to achieve sustainable development.

Specifically, we have set the following preliminary goal: to actively work towards reducing our electricity and water consumption per employee over the coming years, using current consumption levels as a reference point. This goal reflects our commitment to balancing the expansion of our R&D and manufacturing activities with our environmental responsibilities over the next three years. We believe this target is achievable through measures such as upgrading to more energy-efficient equipment, optimizing operational processes to reduce water usage, and enhancing employee awareness. The financial impact of achieving this target is expected to be minimal at the beginning of the timeframe, with potential cost savings from reduced utility expenses becoming more apparent in the interim and at the end of the targeted timeframe. The operational impact will involve implementing stricter monitoring and control procedures for resource consumption.

Policies

To achieve our goals, we have implemented and will continue to enhance the following environmentally friendly measures:

- promoting environmental awareness among all staff by encouraging them to conserve water and electricity resources, such as placing water-saving and power-saving signs in prominent areas;
- encouraging our employees to avoid printing hard copies and requiring double-sided printing whenever possible;
- conducting regular inspections of our laboratory and manufacturing equipment to identify and address inefficiencies promptly; and
- promoting recycling schemes and seeking environmentally friendly ways of disposing of and reducing waste.

Workplace Safety

We are dedicated to ensuring a safe working environment for our employees. We firmly believe that a safe and healthy workplace is not only crucial for the well-being of our employees but also indispensable for the sustainability of our business. We have implemented and upheld a comprehensive set of rules, standard operating procedures, and measures to ensure the health and safety of our employees. Our safety guidelines cover a range of areas including identifying potential hazards, safe practices, accident prevention, and procedures for reporting accidents. We ensure that our employees continually acknowledge their understanding of safety protocols as needed. Specifically, we have (i) established guidelines governing manufacturing and research procedures, (ii) provided regular safety awareness training to our employees, (iii) established systems for occupational disease prevention, (iv) fully inform our employees of the occupational disease factors they may be exposed, (v) maintain health records for all employees and conduct health examinations, (vi) conducted regular fire safety inspections, ensure the maintenance of firefighting equipment, and organize routine emergency drills to prepare employees for emergency situations, and (vii) established effective rescue and response mechanism.

Workplace Diversity

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We hire employees based on their merits. We offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics, and provide training programs to keep our employees abreast of industry and regulatory developments. We have not had any significant workplace accidents since our inception.

Climate Change

We believe that we are not susceptible to climate change. Moreover, we consider that potential changes to the regulations in the PRC regarding climate change will not

adversely impact our business operations. We will continue to pay attention to risks regarding climate change and formulate emergency plans to safeguard us from climate change and extreme weather conditions, such as hurricane and rainstorms. As of the Latest Practicable Date, we had not experienced any material impact on our business operations or financial performance as a result of climate change or extreme weather conditions.

LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may be subject to legal proceedings, investigations, and claims arising from the ordinary course of our business from time to time, and we may also initiate legal proceedings in order to protect our intellectual property and other rights. Our Directors confirmed that, as of the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations, and our Directors were not aware of any potential or threatened legal, arbitral or administrative proceedings to which we will be named as a party. Our Directors further confirm that none of our Directors or senior management personnel was personally involved in any of these legal, arbitral, or administrative proceedings.

Our PRC Legal Advisor confirmed that during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that have led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business. For a discussion of various operational risks and uncertainties we face, please refer to "Risk Factors." We are also exposed to various market risks, particularly the foreign currency risk, interest rate risk, credit risk and liquidity risk that arise in the normal course of our business. Please refer to "Financial Information — Financial Risk Disclosure" for a discussion of the market risks.

We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. The Board is responsible for the oversight of the risk management system and the management is responsible for the design, implementation and monitoring of the system. Risks identified by our management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will continue to adopt, among other things, the following risk management measures.

- Our Audit Committee oversees the overall risks associated with our business operations, including: (i) reviewing policies with respect to accounting and risk management; (ii) discussing with management major issues regarding adequacy and effectiveness of procedures and internal controls over financial reporting; (iii) monitoring our compliance with respect to the legal and regulatory policies; and (iv) reporting regularly to our Board.

- Our management is responsible for: (i) formulating and updating our compliance management policy and objectives; (ii) implementing policies with respect to risk management; (iii) providing guidance regarding compliance with regulations and policies; (iv) identifying and evaluating major risk management issues; (v) supervising and inspecting operating activities of subsidiaries and departments to ensure compliance; (vi) organizing and providing compliance trainings; (vii) providing guidance on our risk management approach to the relevant departments; (viii) reviewing and handling the reporting of wrongdoing; and (ix) reporting to our risk management leader on our material risks.

- The relevant departments in our Company are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments shall: (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their achievement of objectives; (iii) prepare a risk management report annually; (iv) monitor the key risks relating to their operation or function; (v) develop and implement the risk mitigation plans for the key risks identified; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

Internal Control

Our Board of Directors is responsible for ensuring that the Group establishes and maintains an appropriate and effective internal control system so that reasonable assurance can be provided regarding the Group's achievement of objectives relating to operations, reporting and compliance, especially the safeguarding of our Shareholders' investment at all times. Our internal control policies set out the key control measures of various business processes in order to assist the management in communicating the intended practices of these processes and the staff in adopting consistent practices.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding our business operations, and we provide training about these measures and procedures to new employees. We also constantly monitor the implementation of these measures and procedures.

- We maintain strict anti-bribery and anti-corruption policies. Such policies explicitly require that all employees comply with any applicable anti-corruption laws, regulations and policies and that all employees are prohibited from making illegal or improper payments to any government official, including hospital staff, either on their own or via third parties. Additionally, our employees are not allowed to offer or give gifts, hospitality or anything of value that are not an appropriate type or beyond the value limit set forth in the policy. We closely monitor to ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements. Under our firm-wide whistle-blowing policy, we make our internal reporting channel open and available for our employees to report, on an anonymous basis, any noncompliance incidents and acts, including bribery and corruption.

- With respect to the data and privacy protection, the original medical documents relating to test samples in clinical trials are kept by the clinical trial institutions. To improve the privacy protection and data security from our end, the clinical data is de-identified by the clinical trial institutions, ensuring that it does not contain any privacy information of the trial participants. We do not collect participants' personal data, nor are we responsible for clinical data management.

- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our Compliance Advisor, will also periodically review our compliance status with all relevant laws and regulations after the [**REDACTED**].

- We have established an Audit Committee, which is to (i) make recommendations to our Directors on the appointment and removal of external auditors; and (ii) review the financial statements and render advice in respect of financial reporting, as well as oversee internal control procedures of our Group.

Our Directors believe that such controls and measures are sufficient and adequate to avoid the occurrence of corruption, bribery, or other improper conduct of our employees. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any government investigation or litigation with respect to claims or allegations of monetary and non-monetary bribery activities, and to the best knowledge of our Directors, none of our employees were involved in any bribery or kickback arrangements.