OVERVIEW

Founded in 2011, we have been focused on diabetes management, providing both diabetes treatment and diabetes monitoring medical devices to improve the diabetes management in China and globally. We believe that our product portfolio, our advanced positioning in the development of closed loop solutions, our synergistic platform created by integrating our R&D, manufacturing and commercialization capabilities, together with our visionary management team, significantly differentiate us from our peers.

We operate in a large and fast-growing diabetes monitoring, treatment and management market in China and globally with significant unmet clinical needs. Diabetes is one of the most prevalent chronic diseases, which is often frustrating and difficult for patients to manage. According to the CIC Report, the global prevalence of diabetes was 486.9 million people in 2019 and is expected to reach 607.6 million people in 2030. According to the same source, the prevalence of diabetes in China was 118.8 million people in 2019 and is expected to reach 143.2 million people in 2030. The global market size of diabetes management medical devices increased from US$27.8 billion in 2015 to US$42.3 billion in 2020, representing a CAGR of 8.7% from 2015 to 2020, and is expected to increase to US$118.5 billion in 2030, representing a CAGR of 10.9% from 2020 to 2030, with the Chinese market alone to increase from US$0.8 billion in 2015 to US$2.2 billion in 2020, representing a CAGR of 22.0% from 2015 to 2020, and to further increase to US$10.2 billion in 2030, representing a CAGR of 16.7% from 2020 to 2030. Meanwhile, there are significant unmet clinical needs for medical devices that can operate on a real-time and continuous basis to lower the risks of hypo/hyper-glycaemia and offer significant short-term and long-term benefits to patients. Manufacturers are required to have multi- and cross- disciplinary capabilities for the R&D of such innovative medical devices. To capitalize this market opportunity, we were founded in 2011 with the objective to improve the diabetes monitoring, treatment and management through closed loop solutions that dynamically monitor and control the blood glucose level. In addition to Equil, we have two other categories of commercialized products, namely BGMS and CGMS, and six other product candidates at various development stages. According to the CIC Report, BGMS is a traditional method to monitor blood glucose levels and a well-established device, which has been on the market for approximately 40 years.

Equil, our Core Product, is a semi-disposable patch insulin pump. Compared to traditional tubed pumps, Equil features a tubeless and lightweight design, enabling users to manage diabetes discreetly and safely. Other innovative attributes include a vibration alert that users can feel underneath their clothing and a dedicated bolus button that can initiate insulin delivery without the remote control. In September 2017, Equil received the marketing approval for adult use from the NMPA in China. Equil also received CE marking in the EU in the same year. As of the Latest Practicable Date, we had successfully marketed Equil in over 20 countries across Asia Pacific, Europe, Middle East, Africa and Latin America. In February 2021, we submitted a 510(k) premarket notification to the FDA and we expect to receive FDA clearance for Equil in the first half of 2022.

AiDEX G7, our CGMS, is the second commercialized calibration-free real-time CGMS in the world. Since its launch, AiDEX G7 has demonstrated various advantages over traditional BGMS products, featuring real-time monitoring, reduced risk of hyper/hypoglycemia, and increased compliance to treatment regimen without taking routine finger prick blood glucose measurements. AiDEX G7 received CE marking in the EU in September 2020. We completed a clinical trial for AiDEX G7 in China in May 2020 and the NMPA accepted our registration application in the first quarter of 2021. AiDEX G7 has been certified by the NMPA in May 2020 to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA. When approved, AiDEX G7 is expected to be the first calibration-free real-time CGMS approved for commercialization in China.

Besides Equil and AiDEX G7, we have a diverse pipeline of self-developed product candidates with improved features, including our closed loop artificial pancreas, second-generation patch insulin pump system, AiDEX X and IVD devices. The following chart summarizes the development status of our products and major product candidates:

Product Line	Product		Major Markets	Competent Authorities/ Notified Body**	Expected Completion of Current Stage	Expected Commercial Launch
Patch Insulin Pump System	Equil ★	(for adult use)	China	NMPA	N/A	Launched
			EU	TÜV Rheinland**	N/A	Launched
			US	FDA	1H 2022	1H 2022
		(for child and adolescent use)	China	NMPA	1H 2022	2H 2022
	Second-Generation Patch Insulin Pump System		China	NMPA	1H 2022	2H 2023
Continuous Glucose Monitoring System	AiDEX G7	(for adult use)	China	NMPA	2H 2021	2H 2021
			EU	TÜV Rheinland**	N/A	Launched
			US	FDA	1H 2022	1H 2023
		(for child and adolescent use)	China	NMPA	2H 2021	1H 2022
	AiDEX X		China, EU	NMPA, TÜV Rheinland**	2H 2021	1H 2023
Closed Loop Artificial Pancreas	PanCares Artificial Pancreas		China, EU	NMPA, TÜV Rheinland**	1H 2022	2H 2023
	Cloud-based AI-powered Artificial Pancreas		China, EU	NMPA, TÜV Rheinland**	2023	Post 2024
IVD	BGMS Products*		China, EU, US	NMPA, FDA, TÜV Rheinland**	N/A	Launched
	Exactive Pro Glucose, Ketone, Uric Acid Monitoring System		China	NMPA	2H 2021	1H 2022
	IVocare Multifunctional POCT		China	NMPA	2H 2021	2H 2021

★ Core Product

▲ Eligible for NMPA Special Approval Procedures of Innovative Medical Devices

◇ No clinical trial in the U.S. is required for obtaining the 510(k) clearance from the FDA.

* As of the Latest Practicable Date, we had developed and commercialized 15 types of blood glucose meters and seven types of test strips in China, and we had developed and commercialized 12 types of blood glucose meters and six types of test strips in major markets overseas, including the U.S. and the EU.

** Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. In the EU regulatory framework, medical devices are products or equipment intended generally for a medical use and are regulated at Member State level. EU Member States can designate accredited notified bodies ("Notified Bodies") to conduct conformity assessments. In addition to the accreditation by the competent national authority, Notified Bodies are required to become certified under the Annex VII to the MDR. Manufacturers can place a CE mark on a medical device once it has passed a conformity assessment.

Under the MDR, in the case of devices incorporating a medicinal substance, Notified Bodies must seek a scientific opinion from the one of the competent authorities designated by the Member States or from the EMA, a decentralised agency of the EU responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device, before issuing an EU technical documentation assessment. As of the Latest Practicable Date, none of our products commercialized in Europe fall into such category.

TÜV Rheinland is a certified Notified Body within the EU, to evaluate medical devices for CE marking and marketing in the EU, including the eight EU Member States where we commenced the commercialization of Equil, i.e., Italy, Austria, Greece, Czech Republic, Slovakia, Bulgaria, the Netherlands and Poland.

As we build up our product pipeline, we have developed a synergistic platform by integrating our R&D, manufacturing and commercialization capabilities.

- *R&D*. We had a proven record of R&D experience. We were designated as the Key Diabetes Research Center in Zhejiang Province, China, and we had also established a R&D center in Silicon Valley. Equil, our Core Product, was designated as an Innovative Medical Device Product by the PRC Ministry of Science and Technology. Led by Dr. Zheng Pan, our Chief Executive Officer, who has nearly 20 years of experience in the healthcare industry, we have formed an in-house R&D team of nearly 100 staff with extensive industry experience and multidisciplinary capabilities. We remain at the forefront of innovation by maintaining close contact with leading medical professionals and KOLs and develop products that specifically address the unmet clinical needs. We leverage our R&D capabilities to develop high-quality closed loop solutions, patch insulin pump systems and CGMS products in a cost-effective manner.

- *Manufacturing*. We conduct all the key manufacturing procedures in-house. Over the years, we have accumulated extensive expertise and know-how in manufacturing diabetes management medical devices, which sets a solid foundation for our long-term growth. We own manufacturing facilities with an aggregate area of approximately 15,000 sq.m. in Hangzhou, China, including a 1,500 sq.m. ISO Class 7 clean-room space and an 80 sq.m. ISO Class 8 clean-room space. We uphold manufacturing quality management, and have received major international certifications. Our emphasis on the automatic and continuous control of manufacturing processes also significantly contributes to the improvement of our overall production quality and efficiency.

- *Commercialization*. We strategically use a combination of our in-house sales and marketing team and a broad network of independent distributors to sell our products in China and overseas. We had 382 distributors as of April 30, 2021 and over 130 in-house sales and marketing personnel as of the Latest Practicable Date, covering the sales of our products across 30 provinces, municipalities and autonomous regions in China, and expanding the sales of our products to overseas markets.

Our large portfolio of marketed products and diversified product offerings encompassing diabetes treatment and diabetes monitoring medical devices have enabled us to achieve rapid growth. Furthermore, we are currently in the early stage of marketing our CGMS. We expect our business will continue to grow, as we ramp up the sales of our patch insulin pump system and CGMS, and commence the marketing of our closed loop solutions, in particular, our artificial pancreas.

As our product portfolio diversifies, we are making efforts in the design and training of control algorithms for our closed loop solutions. We are also seeking to synthesize advanced analytical tools and AI to gain in-depth insights into diabetes management.

We aspire to significantly improve treatment outcomes and improve the diabetes monitoring, treatment and management in China and globally. To achieve such aspiration, we will keep improving the features and quality of our products, developing our R&D capabilities, expanding our global footprint and building a cloud-based diabetes management platform to bring clinical and commercial benefits to diabetes patients all over the world.

OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors.

Proven capability of improving the diabetes management in China and globally through diabetes treatment and monitoring devices

We have developed proven capability of improving the diabetes management in China and globally through the development of closed loop solutions, such as the artificial pancreas, that integrate the continuous treatment and monitoring of diabetes to meet the significant unmet clinical needs. Such closed loop solutions will require two essential components: a continuous insulin delivery system that provides background and on demand insulin dosages that compensate for blood glucose fluctuations and a CGMS that provides real-time monitoring of glucose levels.

We believe that these two commercial-stage products have paved the way for us to internally develop the closed loop artificial pancreas without the need to seek collaborations for complementary technologies. More importantly, the united features of our patch insulin pump system and CGMS will benefit us in the research, development and commercialization of closed loop solutions in the following aspects:

- *Deep integration*: Enable us to create a cohesive and user-friendly ecosystem of products with deep integration, as opposed to those with fragmented technologies attempting to work at many levels;

- *Unified design*: Enable us to leverage the user feedback collected from the users of one product in the design, development and optimization of the other;

- *Unified implementation*: Enable us to share common components between our CGMS and patch insulin pump system, which will reduce the complexity and cost for replacements and optimize the user experience;

- *Unified manufacturing and quality systems*: Enable us to improve operational and cost efficiency through unified manufacturing and quality control systems;

- *Unified data platform*: Enable users and healthcare institutions to receive and share data in a unified data platform provided by us, rather than from separate glucose monitoring and insulin delivery device companies; and

- *Unified sales and service*: Enable us to offer one-stop sales and services of both continuous glucose monitoring and insulin delivery systems to users.

In addition, we are seeking to harness big data analytics and AI technologies to further improve the software and the hardware of our existing products and our closed loop solutions under development.

With our product portfolio, years of experience and technological advances, we believe that we are well-positioned to bring to market real-time, highly accurate, user-friendly and affordable closed loop solutions, including the artificial pancreas, which could rapidly penetrate the diabetes market and improve the diabetes management.

The first and only patch insulin pump approved in China

Insulin pumps are continuous subcutaneous insulin infusion ("**CSII**") therapy devices used for administering insulin infusion in diabetes treatment. CSII therapy has been shown to provide better glycemic control and increased lifestyle flexibility for patients requiring insulin-dependent therapies. In China, CSII therapy has been included in the clinical guidelines for treatment of Type 1 and Type 2 diabetes. CSII therapy has also been recognized and recommended for use in short-term insulin intensive therapy. Coupled with wider adoption of CSII therapy, there has been a growing market demand for insulin pumps. According to the CIC Report, the global market size of the insulin pump market increased from US$4.1 billion in 2015 to US$5.6 billion in 2020 representing a CAGR of 6.6% from 2015 to 2020 and is expected to reach US$20.7 billion in 2030 representing a CAGR of 14.0% from 2020 to 2030; and the market size of the insulin pump market in China increased from US$58.1 million in 2015 to US$125.4 million in 2020 representing a CAGR of 16.6% from 2015 to 2020 and is expected to reach US$1.0 billion in 2030 representing a CAGR of 23.3% from 2020 to 2030.

Currently, tubed insulin pumps and tubeless patch insulin pumps are the two main types of insulin pumps. Patch insulin pumps are found to be significantly better than traditional tubed insulin pumps, as they avoid tubing issues and increase patients' adherence treatment regiments by featuring tubeless, smaller device size, and greater portability. Equil is a semi-disposable patch insulin pump. Among all the insulin pump products currently approved in China, Equil is the only patch insulin pump. In particular, compared to its commercialized peer products, Equil has longer reusable lifetime, rechargeable battery and unique vibration alert in the pump design. The comparison of Equil with its commercialized peer products are further illustrated in the chart below:

Company **Product name**	**The Company** **Equil**	**Insulet** **Omnipod-Dash System**	**Roche** **Accu-check Solo**
Pump	Semi-disposable	Disposable, one-time use	Semi-disposable
Duration of pump body	Four years	Three days	Four months
Weight with battery and insulin	28g	27g	29g
Battery rechargeable or not	Rechargeable battery	Non-rechargeable battery	Non-rechargeable battery
Bolus button	Yes	No	Yes
Alarms	Patch pump: LED and vibration Remote: LED, sound, and vibration	Pod: LED and sound Remote: LED and sound	Pump: sound and LED Remote: visual, sound and LED
Convenience	The pump body can be removed from the body as needed, and can be reattached	Pod cannot be reused if removed from the body	The micropump can be removed and reattached
Regulatory	Compliant with applicable NMPA regulations	Adjustments may be required to comply with applicable NMPA regulations	FDA and CE
Delivery specs	Minimum step size: 0.025U	Minimum step size: 0.050U	Minimum step size: 0.01U*
Repair or replacement warranty	√	√	√
Warranty period	Four years	Four years	Four years
Pump requires wireless remote/PDA	√	√	√
Smartphone app	×	√	×
Is the pump a hybrid closed-loop device	×	×	×
Daily cost in the U.S. (in USD)	Not approved	10	Not approved
Daily cost in the EU (in USD)	<10	10~15	20~25
Marketed Regions	China, EU	The U.S., EU	EU
Approval time	China: 2017.08 EU: 2017.06	The U.S.: 2018.06 EU: 2019.09	EU: 2018.07

* Only allow the minimum 0.01U increment for basal rates set between 0.1-0.5U/hr

Source: CIC Report, FDA, NMPA

As of the Latest Practicable Date, we had successfully marketed Equil in over 20 countries across Asia Pacific, Europe, Middle East, Africa and Latin America. We are also developing our second-generation patch insulin pump system, featuring smaller size, improved waterproof performance, better adaptability to insulin reservoirs in different sizes, and augmented user-friendliness. The insulin pump, as a continuous insulin delivery device, is also an essential component of closed loop artificial pancreas. We expect to equip our second-generation patch insulin pump system with internal control algorithms, which, together with our CGMS, is expected to form the bedrock of our closed loop artificial pancreas.

Major player in the field of CGMS with a product portfolio across multiple product lines in-house

Our first CGMS, AiDEX G7, is the second commercialized calibration-free real-time CGMS in the world.

In recent years, CGMS has been quickly penetrating the diabetes monitoring medical devices market and gradually replacing the conventional BGMS. According to the CIC Report, the global market size of CGMS increased from US$1.7 billion in 2015 to US$5.7 billion in 2020, representing a CAGR of 28.2% from 2015 to 2020, and is expected to reach US$36.5 billion in 2030, representing a CAGR of 20.3% from 2020 to 2030. Compared to BGMS, CGMS offers greater usability. BGMS usually involves unpleasant blood draws using finger pricks. Users also need to reload a disposable strip into the blood glucose meter every time reading is taken. By contrast, a growing number of CGMS products are calibration-free (i.e., no finger-prick calibration), which measure and record glucose levels in real time every one to five minutes without the pain of finger-pricking. CGMS promotes better adherence to treatment regimens in diabetes patients by simplifying and making the process of glucose monitoring and management pain free.

AiDEX G7 enjoys favorable commercialization positioning in China and globally. We completed a clinical trial for AiDEX G7 in China in May 2020 and the NMPA accepted our registration application in the first quarter of 2021. AiDEX G7 has been certified by the NMPA in May 2020 to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA. When approved, AiDEX G7 is expected to be the first calibration-free CGMS approved for commercialization in China that addresses the significant unmet clinical needs. AiDEX G7 received CE marking in September 2020, and we started to commercialize AiDEX G7 in Europe in March 2021.

The comparison of AiDEX G7 with its commercialized peer products is demonstrated in the chart below:

Performance	The Company's AiDEX G7	Abbott Libre	Medtronic Guardian	Dexcom G6
Calibration	Calibration-free	Calibration-free	Twice per day	Calibration-free
Usage Time	14 days	14 days	7 days	10 days
Startup Time	1 hour	1 hour	2 hours	2 hours
Transmitter Life	4 years	1 year (sensor integration)	1 year	3 months
Frequency of Readings	5 min (realtime)	15 min (retrospective)	5 min (realtime)	5 min (realtime)
Alarm Functions	Realtime high and low glucose alarm	None	Realtime high and low glucose alarm	Realtime high and low glucose alarm
Built in Traditional Meter	Included	Included	None	None
Accuracy (MARD)(1)	9.1%	12.1%	9.1-10.6%	9.0%
Picture				

Note:

(1) MARD refers to the mean absolute relative difference, which is the average value of the absolute error between the CGMS detection value and the referenced value. The lower the value, the higher the accuracy.

Source: CIC Report

CGMS can also assist in scenarios where monitoring irregular glucose fluctuation is required or recommended, such as health precaution. As a result, there has been a growing trend for expanding the application of CGMS in these fields. Besides AiDEX G7, we are leveraging our proprietary technologies to develop the second-generation calibration-free CGMS – AiDEX X to better address such untapped opportunities. AiDEX X is designed for non-intensive diabetics, pre-diabetics, and health-aware non-diabetic users, who focus more on ease of use, cost-efficiency and ultra-portability. We believe that by synergistically addressing different target populations, AiDEX G7 and AiDEX X will complement each other, and will allow us to deploy a portfolio approach, enabling rapid market penetration and wide user coverage. Our CGMS products will also constitute as an essential component of our closed loop artificial pancreas.

Focus on designing and developing the artificial pancreas by integrating insulin pump and CGMS with AI-optimized algorithms

We had initiated the design and the development of our first closed loop solution, the artificial pancreas, as of the Latest Practicable Date. When approved, our artificial pancreas will likely become the world's first closed loop solution that integrates the self-developed calibration-free CGMS and patch insulin pump system.

Artificial pancreas has long been viewed as one of the disruptive solutions to the monitoring, treatment and management of diabetes. Deployed by a series of control algorithms, an artificial pancreas effectively combines the insulin pump and CGMS to monitor, treat and manage the blood glucose level on a real-time and continuous basis. Instead of delivering insulin and monitoring the glucose in a static and fragmented manner, an artificial pancreas closely mimics the action of a normally-functioning pancreas, which allows a dynamic and closed loop management of blood glucose levels. Artificial pancreas enables automatic adjustments of insulin delivery guided by the continuous monitoring of glucose level. Artificial pancreas can increase the time in target glycemic range, and reduce the risk of hyperglycemia or hypoglycemia, with minimum input from the patient. According to the CIC Report, the market size of the global artificial pancreas market increased from US$0.5 billion in 2017 to US$1.1 billion in 2020 representing a CAGR of 26.4% from 2015 to 2020, and is expected to reach US$6.7 billion in 2030, representing a CAGR of 20.4% from 2020 to 2030.

Our artificial pancreas under development will be an integration of our patch insulin pump system and CGMS. Leveraging our experience and industry knowledge, we have preliminarily constructed the control algorithms, performed the multi-parameter simulation and analysis, and conducted the stress tests on the safety of such product candidate. Featuring closed loop control, we believe our artificial pancreas will fundamentally improve the monitoring, treatment and management of diabetes. We are also in the process of designing and developing a cloud-based AI-powered artificial pancreas, which will also form an integral part of our closed loop solutions. The platform will be a central repository of data collected through our CGMS on an anonymous basis. The platform will synthesize advanced analytical tools, function through data-driven, AI-powered algorithms and will be subject to continuous optimization.

Synergistic platform with integrated R&D, manufacturing and commercialization capabilities

We have developed a synergistic platform with integrated R&D, manufacturing and commercialization capabilities. We are at the inflection point to further leverage such platform and improve our financial and operating performance to achieve economies of scale.

R&D

We have an in-house R&D team of nearly 100 staff, led by Dr. Zheng Pan, our Chief Executive Officer, who brings us nearly 20 years of industry leadership experience. Dr. Zheng has led a project under a National Major Scientific Research Program in 13th Five-Year Plan Period, namely, Construction and Application of a Cloud-based AI Diabetes Management Platform for Children and Adolescents with Diabetes. Led by Dr. Zheng Pan, our team focused on the R&D of an intelligent cognitive computed based closed loop artificial pancreas was also awarded as "Leading Innovative Team" by the Science and Technology Department of Zhejiang Province.

Over 30% of our R&D staff possess a master or doctorate degree, and they have extensive R&D experience at leading medical device companies, including Flex (or known as Flextronics), Medtronic, Johnson and Johnson, and Terumo. Among our core R&D staff, Mr. Dore Chin Mark, our vice president for engineering has over 20 years of industry experience. Mr. Dore Chin Mark has successfully led the launch of a series of medical device products overseas, and he is the inventor of more than 10 issued patents and designs in the U.S. Dr. Yu Fei, our R&D director, is an outstanding scientist in the field of bioelectric chemistry. Dr. Yu Fei has accumulated years of experience in the R&D of diabetes management medical devices. Dr. Yu Fei is the inventor of more than 10 issued patents relating to the biosignal detection. Dr. Yu Fei is also the reviewer of five leading journals, including Biosensor & Bioelectronics, IEEE Sensor and PLOS One. Our R&D team has also developed outstanding interdisciplinary capabilities in the field of mechanical engineering, electrical engineering, software engineering, communication engineering and signal processing, electrochemistry, biomedical engineering and mathematics (algorithm) and artificial intelligence.

Externally, we have built long-standing relationship with industry KOLs including well-known medical professionals and clinical experts. We leverage their meaningful insights and recommendations to steer our R&D process towards the unmet clinical needs. Our long-term collaborations with leading universities and research institutions also enable us to cultivate a high-quality talent pool, and explore frontier and breakthrough technologies.

In recognition of our R&D capability, we were designated as the Key Diabetes Research Center in Zhejiang Province, China. Equil was designated as an Innovative Medical Device Product by the PRC Ministry of Science and Technology. AiDEX G7 has been certified by the NMPA in May 2020 to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA.

Manufacturing

Since our inception, we have focused on building our internal manufacturing capabilities that meet rigorous international standards. We have accumulated extensive expertise and know-how in manufacturing medical devices and IVD medical devices. As of the Latest Practicable Date, we owned manufacturing facilities with an aggregate area of approximately 15,000 sq.m. in Hangzhou, China, including a 1,500 sq.m. ISO Class 7 clean-room space and an 80 sq.m. ISO Class 8 clean-room space, for the production and pre-delivery inspection of our products. We have received major international certifications for our manufacturing quality management, demonstrating our manufacturing capabilities and commitment to high quality. Our manufacturing facilities comply with the GMP requirements, and our quality management system conforms to the ISO 13485 standard, among others.

By internally designing, implementing and optimizing our manufacturing processes and procedures leveraging our accumulated know-how, we are able to monitor and continuously improve the manufacturing efficiency and quality, and achieve significant cost advantages. Furthermore, we have also implemented a series of automation initiatives throughout the entire manufacturing process. The automatic and continuous control of our manufacturing processes significantly contributes to the improvement of our overall production quality and efficiency. We believe our ability to deliver safe and high quality products also enables us to accelerate product registration and expand our market reach in China and globally.

Commercialization

We strategically use a combination of our in-house sales and marketing team and a broad network of independent distributors to market our products. We had over 130 in-house sales and marketing personnel as of the Latest Practicable Date. Our core sales personnel have on average more than 15 years of experience working in the relevant field.

In addition, we had built a network of 382 distributors as of April 30, 2021, covering the sales of our products across 30 provinces, municipalities and autonomous regions in China, and expanding the sales of our products to overseas markets.

We leverage our diversified commercialization approach to generate greater market demand of our products:

- *User-centric and clinical-data-driven promotion.* To promote the knowledge of the clinical benefits of our products and enhance our brand awareness, we deeply engage with healthcare professionals and patients by providing on-site demonstration, training and education programs using our products. Once a product has been launched, our sales team and distributors continue to gather timely clinical feedbacks through regular visits and follow-up communications, which facilities the ongoing upgrade of our products. To share our clinical findings and showcase the benefits of our products, we also regularly organize and attend educational symposia, conferences and seminars, and other activities at national, regional and

local levels, that gathered leading KOLs and experts focused on the treatment of diabetes, including the International Congress of Immunology of Diabetes Society, China Diabetes Society Annual Meeting and Endocrinology Society of China Annual Meeting.

- *Collaboration with commercial insurers.* We are seeking to collaborate with leading commercial insurers, such as Taikang Insurance Group Inc., to expand diabetes patients' access to our advanced diabetes monitoring, treatment and management products. We believe this approach will not only ramp up our market share and gain significant pricing flexibility, but also improve the overall prevention and treatment penetration among diabetes population. As additional products from our pipeline are registered in China, we also intend to seek national insurance coverage to further increase market access.

We believe our commercialization capabilities and efficiencies have strengthened throughout the process. As of the Latest Practicable Date, Equil had been sold or distributed into 805 hospitals in China. Shortly after AiDEX G7 obtained CE marking in September 2020, we completed the first shipment of AiDEX G7 to Europe.

Visionary management team of industry veterans and industry-leading investors

We believe that our success attributes to our management's leadership and expertise, which cover the full spectrum of the medical device development cycle of design, clinical development, manufacturing and commercialization, as well as the continuous support from industry leading investors.

Dr. Zheng Pan, our Chief Executive Officer, has nearly 20 years of experience in the healthcare industry with a solid track record in designing and developing innovative medical devices. Dr. Zheng Pan has dedicated his career to applying breakthrough technologies to medical devices indicated for diabetes treatment and management. Dr. Zheng Pan is supported by a management team of industry veterans. Dr. Yu Fei, our R&D director, Mr. Dore Chin Mark, our vice president for engineering, and Mr. Lan Yi, our vice president for sales have on average 20 years of experience in the relevant field. Prior to joining us, they have served on various management positions at major pharmaceutical and medical device companies, such as Eli Lilly, Johnson & Johnson, Medtronic and Flex (also known as Flextronics). In addition, we have a growing pool of high-quality talent to support our seasoned management team in achieving our mission.

Since our establishment, we have received investments from industry-leading investors, including strategic investors Tencent and Taikang, and financial investors such as Lilly Asia Ventures, Qiming Venture Partners, IDG Capital, 3H Health and CICC Pucheng. This strong investor base is a testament to our vision and capabilities. These investors have also provided strategic advice and guidance to our research and development and the operational management.

OUR STRATEGIES

Our objective in the mid-term is to leverage our strengths in patch insulin pump system and CGMS to continue to grow sales, develop and launch our closed loop solutions, increase our brand awareness and expand our global footprint. In the long term, we aim to build a cloud-based diabetes management platform to bring clinical and commercial benefits to diabetes patients all over the world. To achieve these objectives, we intend to pursue the following strategies.

Advance diabetes monitoring, treatment and management around the globe with our diversified product portfolio

We intend to broaden our pipeline through indication expansion, advance and upgrade our current products, and continue to seek regulatory approval of our products in China, the U.S., Europe and other key geographies.

We will pragmatically evaluate indication expansion and perform subsequent clinical development that will expand the labels of our products. Currently, we are seeking to expand the use of Equil and AiDEX G7 to children and adolescents with diabetes. With respect to the expansion of the use of Equil to children and adolescents, we expect to complete the registrational clinical trials in China and submit the registration application to the NMPA in the first half of 2022. In addition, we intend to invest in the development of our second-generation patch insulin pump system, which is designed to have smaller size, reliable waterproof performance, better adaptability and improved user-friendliness. Meanwhile, we are developing AiDEX X, a CGMS designed for non-intensive diabetics, pre-diabetics and health-aware non-diabetic users. We have completed the feasibility analysis of our second-generation patch insulin pump system and AiDEX X. We expect to complete the relevant registrational clinical trial and submit the relevant registration application to the NMPA for our second-generation patch insulin pump system and AiDEX X in the first half of 2023 and the second half of 2022, respectively.

Furthermore, we will continue developing our closed loop solutions, in particular, artificial pancreas, which will provide an integrated solution for the monitoring, treatment and management of diabetes. We will equip our second-generation patch insulin pump system with control algorithms, which, together with our CGMS, is expected to form the bedrock of our closed loop artificial pancreas. We are currently testing our proprietary control algorithms, and aim to initiate the registrational clinical trial for our closed loop artificial pancreas in the first half of 2022 in China, and a registrational clinical trial in the U.S. is also under plan. We expect to title our products, in particular, our closed loop solutions, including the artificial pancreas, with high class of recommendation and level of evidence in relevant guidelines published by authorities in China, the U.S. and the EU.

We will continue to improve and expedite the introduction of our patch insulin pump system and CGMS to major markets. We completed a clinical trial for AiDEX G7 in China in May 2020 and the NMPA has accepted our registration application in the first quarter of 2021. AiDEX G7 has been certified by the NMPA in May 2020 to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA. When approved, AiDEX G7 is expected to be the first calibration-free real-time CGMS approved for commercialization in China. We are seeking the FDA approval of Equil for the treatment of diabetes in adult patients, and the registration application has been filed with the FDA in February 2021. We plan to continue our clinical and academic efforts, including through post-launch studies, after receiving the marketing approval for our existing and future products.

Continue to develop our multidisciplinary R&D capabilities and address the evolving clinical demands

To solidify our industry leadership and competitiveness, we plan to continue developing our R&D capabilities through a multidisciplinary approach and integrate advanced technologies in the field of material science, microfabrication, bioinformatics, cloud-based computation and artificial intelligence. We have strategically established and will maintain and expand our partnerships with leading universities and science and technology institutes. For example, we have jointly established the Flexible Electronics Joint R&D Center with Zhejiang University. We anticipate these efforts will deepen our technology research in diabetes management medical devices and bring tangible results in the future.

In parallel, we will augment our translational research to expedite our bench-to-bedside development process, transforming latest technological advancement into clinically validated solutions. Our collaborations with major research-oriented hospitals, diabetes research institutions will provide us with visibility into the clinical potentials of our product pipeline. We will also maintain periodic communications with industry KOLs and frontline medical practitioners. We believe their first-hand feedback on unmet clinical needs will pivot our product development and upgrade, and allow us to adopt effective marketing strategies to address the evolving clinical demands in a timely manner. In addition, we will continue to launch research funds and encourage researchers and physicians to explore the use of our technologies in new clinical applications and therapies and facilitate our continuing product pipeline expansion.

Continue to expand our global footprint through a user-centric and clinical-data-driven sales strategy and a diversified commercialization channel

We are committed to sales and marketing through a highly specialized in-house sales and marketing team and a strong global distribution network covering the sales of our products across 30 provinces, municipalities and autonomous regions in China, and expanding the sales of our products to overseas markets.

We will continue to expand our global footprint by recruiting high-caliber sales staff with extensive local experience. For example, our current EU sales director has nearly 20 years of experience in the marketing of diabetes management medical devices in Europe, who also has an in-depth knowledge of continuous glucose monitoring and CSII therapy. We believe these industry veteran will enable us to fully unlock the potential commercial value of our products in major markets. Furthermore, we will explore opportunities to maintain and establish long-term cooperation with leading distribution partners who have strong local network, on-the-ground experience and knowhow to complement and further strengthen our market presence.

We strive to implement and enhance our user-centric and clinical-data-driven sales strategy. We plan to retain strong relationship with industry KOLs, as we believe that a strong relationship with KOLs will be important in influencing hospital or users' buying decisions. We will continue to actively organize and participate in academic conferences and activities and utilize scientific presentations and publications to drive the awareness of our brand and products. In light of the chronic nature of diabetes, we will focus on rendering continuous supports to healthcare professionals and patients. These clinical feedbacks are critical to launching high-quality products and bring optimal clinical outcomes to the population suffering from diabetes or abnormal glucose level.

Furthermore, we will continue to diversify our commercialization channel by garnering appropriate reimbursement and insurance coverage of our products, including through collaboration with Taikang and other commercial insurance partners and public insurance programs. Such effort will reduce patients' cost, and increase our market penetration without compromising the quality of our care.

Continue to increase our manufacturing capacity to support our growth and achieve economies of scale

We are committed to continuously expanding our manufacturing facilities and improving our quality management system. We will continue to design and establish our manufacturing facilities and production lines in accordance with international standards, invest in state-of-the-art manufacturing equipment, and automate production capabilities to better address market demand while capturing economies of scale. We have been upholding and will continue to uphold a high standard of quality. Our manufacturing systems have obtained GMP

certifications and complied with requirements by competent authorities. We plan to leverage our strong track record and experience to obtain additional certifications and adopt advanced standards for ongoing overseas expansion.

Build a cloud-based diabetes management platform to enable the formulation of personalized diabetes solutions and a closed loop diabetes management ecosystem

Aside from leveraging our enriched and diversified portfolio to improve the diabetes management through innovating and integrating the treatment and monitoring of diabetes, we also strive to build a cloud-based diabetes management platform to provide continuous, proactive and personalized diabetes management solutions worldwide. We believe clinical data and insights accumulated through the growing use of our products are not only useful to the R&D of our closed loop solutions, but also of great value for optimizing the outcome of diabetes treatment and management. However, mismatch between the sheer amount of data available and the limited time frustrates the ability of physicians to offer personalized and in-depth analysis remains unsolved.

To address this challenge, we intend to develop and continuously optimize a cloud-based diabetes management platform, utilizing artificial intelligence, big data analytics and cloud computing technologies. We believe a platform empowered by these advanced technologies will facilitate the effective organization and evaluation of the vast amount data and information. Relying on such platform, we will be able to create a closed loop diabetes management ecosystem to improve the quality of care for patients with diabetes, increase our market penetration, and enhance user stickiness.

OUR PRODUCTS AND PRODUCT PIPELINE

We have been focused on diabetes management, providing both diabetes treatment medical devices and diabetes monitoring medical devices to improve the diabetes management in China and globally. Established in 2011, we are dedicated to helping people with diabetes lead healthier lives. We have a product portfolio for diabetes monitoring, treatment and management, across multiple product lines, including patch insulin pump system and CGMS, which form the basis of the closed loop artificial pancreas, as well as IVD devices, such as BGMS and POCT devices. As of the Latest Practicable Date, all of our products and product candidates were self-developed and did not involve in-license arrangements with third-parties. Equil, our patch insulin pump system, was approved by the NMPA as a Class III medical device and constitutes our Core Product for purposes of this Document. Our product candidates are subject to approval by relevant authorities in China, the U.S. and the EU, before commercialization in relevant jurisdiction. For details, see "Regulatory Overview." As of the date of this Document, we had not received any material comments or concerns raised by the relevant regulatory authorities with respect to our Core Product that we are not able to address in a timely manner, and we believe we are on track to file for approval related to our product candidates as described in "—Our Products and Product Pipeline."

Besides Equil and AiDEX G7, we have a diverse pipeline of self-developed product candidates with improved features, including our closed loop artificial pancreas, second-generation patch insulin pump system, AiDEX X and IVD devices. The following chart summarizes the development status of our products and major product candidates:

Product Line	Product		Major Markets	Competent Authorities/ Notified Body**	Preclinical / Clinical / Registration / Commercialization	Expected Completion of Current Stage	Expected Commercial Launch
Patch Insulin Pump System	Equil ★	(for adult use)	China	NMPA		N/A	Launched
			EU	TÜV Rheinland**		N/A	Launched
			US	FDA		1H 2022	1H 2022
		(for child and adolescent use)	China	NMPA		1H 2022	2H 2022
	Second-Generation Patch Insulin Pump System		China	NMPA		1H 2022	2H 2023
Continuous Glucose Monitoring System	AiDEX G7	(for adult use)	China	NMPA	▲	2H 2021	2H 2021
			EU	TÜV Rheinland**		N/A	Launched
			US	FDA	◇	1H 2022	1H 2023
		(for child and adolescent use)	China	NMPA		2H 2021	1H 2022
	AiDEX X		China, EU	NMPA, TÜV Rheinland**		2H 2021	1H 2023
Closed Loop Artificial Pancreas	PanCares Artificial Pancreas		China, EU	NMPA, TÜV Rheinland**		1H 2022	2H 2023
	Cloud-based AI-powered Artificial Pancreas		China, EU	NMPA, TÜV Rheinland**		2023	Post 2024
IVD	BGMS Products*		China, EU, US	NMPA, FDA, TÜV Rheinland**		N/A	Launched
	Exactive Pro Glucose, Ketone, Uric Acid Monitoring System		China	NMPA		2H 2021	1H 2022
	IVocare Multifunctional POCT		China	NMPA		2H 2021	2H 2021

★ Core Product

▲ Eligible for NMPA Special Approval Procedures of Innovative Medical Devices

◇ No clinical trial in the U.S. is required for obtaining the 510(k) clearance from the FDA.

* As of the Latest Practicable Date, we had developed and commercialized 15 types of blood glucose meters and seven types of test strips in China, and we had developed and commercialized 12 types of blood glucose meters and six types of test strips in major markets overseas, including the U.S. and the EU.

** Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. In the EU regulatory framework, medical devices are products or equipment intended generally for a medical use and are regulated at Member State level. EU Member States can designate accredited notified bodies ("Notified Bodies") to conduct conformity assessments. In addition to the accreditation by the competent national authority, Notified Bodies are required to become certified under the Annex VII to the MDR. Manufacturers can place a CE mark on a medical device once it has passed a conformity assessment.

Under the MDR, in the case of devices incorporating a medicinal substance, Notified Bodies must seek a scientific opinion from the one of the competent authorities designated by the Member States or from the EMA, a decentralised agency of the EU responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device, before issuing an EU technical documentation assessment. As of the Latest Practicable Date, none of our products commercialized in Europe fall into such category.

TÜV Rheinland is a certified Notified Body within the EU, to evaluate medical devices for CE marking and marketing in the EU, including the eight EU Member States where we commenced the commercialization of Equil, i.e., Italy, Austria, Greece, Czech Republic, Slovakia, Bulgaria, the Netherlands and Poland.

Equil – Core Product

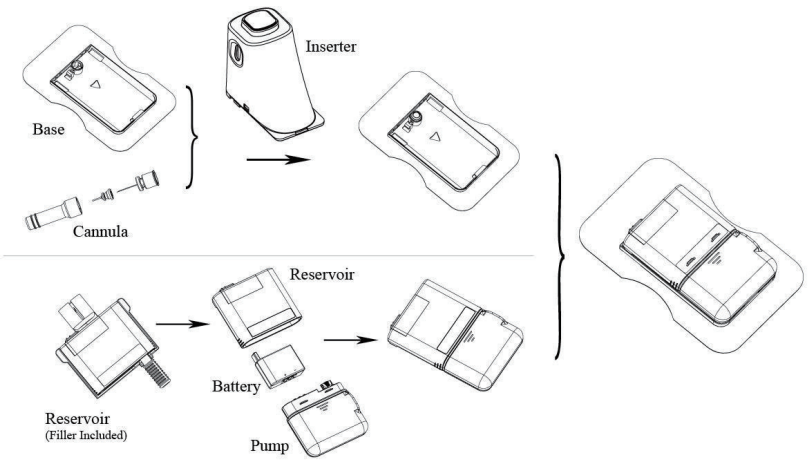
Our Core Product Equil is a tubeless patch pump worn directly on the body that combines the pumping mechanism and infusion set in a small wearable package.

Insulin pumps are intended for continuous subcutaneous insulin infusion ("**CSII**"). A traditional tubed pump has a pumping mechanism combined with an insulin reservoir that delivers insulin through a long tube into an infusion set worn on the body. The large pump body contains buttons that allow the users to program bolus insulin for meals or high glucose correction, to specific basal rates for background insulin, or to suspend the insulin infusion altogether, if necessary. In contrast, patch pumps are controlled wirelessly by a separate device that allows programming of basal rate of infusion and bolus insulin for meals and other activities to the tubeless patch pump. Patch pumps can eliminate the inconvenience of the external tubing required by a traditional tubed pump and reduce the risk of therapy obstructions caused by external tubes being kinked, bent or pulled.

Equil received CE marking in Europe in June 2017 and the marketing approval by the NMPA, for adult use, in China in September 2017. We started to commercialize Equil in China and Europe in 2018. Our revenue generated from Equil increased from RMB24.7 million in 2019 to RMB34.7 million in 2020, and increased from RMB8.3 million for the four months ended April 30, 2020 to RMB19.6 million for the same period of 2021. Our gross profit generated from Equil increased from RMB17.7 million in 2019 to RMB25.2 million in 2020, and increased from RMB6.1 million for the four months ended April 30, 2020 to RMB15.4 million for the same period of 2021. The gross profit margin of Equil increased from 71.8% in 2019 to 72.5% in 2020, and increased from 73.6% for the four months ended April 30, 2020 to 78.5% for the same period of 2021. The sales volume of the patch pump and PDA of Equil increased from 2,765 units in 2019 to 4,084 units in 2020, and increased from 830 units for the four months ended April 30, 2020 to 1,815 units for the same period of 2021. The sales volume of the disposables of Equil increased from 285,503 units in 2019 to 595,640 units in 2020, and increased from 67,134 units for the four months ended April 30, 2020 to 282,891 units for the same period of 2021. During the Track Record Period, the retail price of our Equil was RMB28,800 per unit in China and €2,500-3,000 per unit in Europe. We generally do not sell PDA of Equil on a standalone basis and the recommended retail price of PDA is RMB5,000 in China. The foregoing retail price of Equil does not take into account of the disposables. During the Track Record Period, the retail price of disposables of Equil (including a disposable insulin reservoir and a disposable infusion set) per unit was RMB80 in China and €15 to €20 per unit in Europe. We did not experience any material fluctuations in the retail price of Equil in China and Europe. For factors affecting the retail price of Equil, see "—Pricing". We have submitted a 510(k) premarket notification for Equil to the FDA in February 2021, and we expect to receive the FDA clearance in the first half of 2022. We had been engaged in the research and development on the expansion of the use of Equil to children and adolescents (aged 3 to 18 years old) since the second quarter of 2019. Currently, we are preparing for a pivotal clinical trial in China for purposes of registering Equil for children and adolescents' use. We will also continue developing our second-generation patch insulin pump system and artificial pancreas, with Equil serving as an essential component.

Product Design and Technology

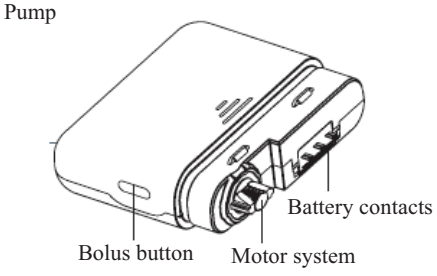
As demonstrated below, Equil comprises (i) a reusable section, consisting of a patch pump and a self-designed wireless portable diabetes assistant ("**PDA**"), and (ii) disposables, including a disposable insulin reservoir and a disposable infusion set.



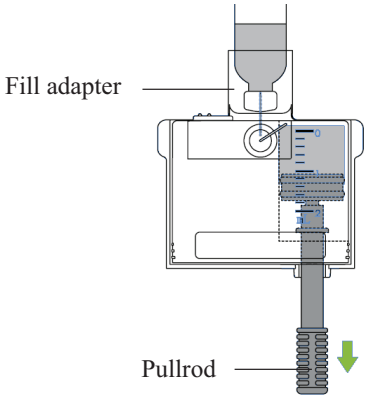
PDA

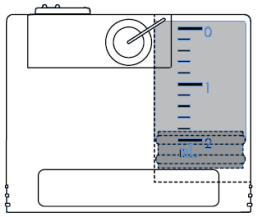
Patch pump

The patch pump is a small, lightweight, wearable, semi-disposable device integrating an insulin reservoir and an infusion set. The patch pump can be attached to multiple body sites and can be easily hidden beneath clothing, which addresses the discreetness concerns of users and provides great convenience.



Insulin reservoir



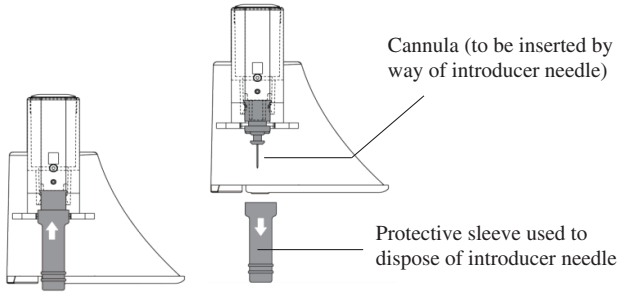


Insulin reservoir
(without fill adapter and pullrod)

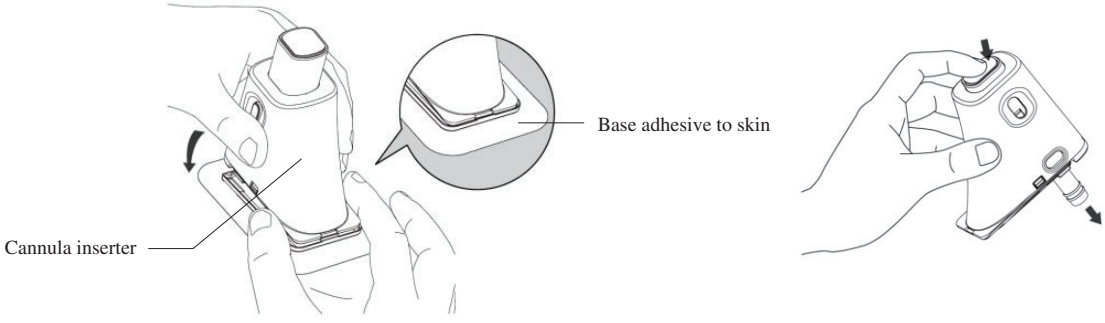
Infusion set

The infusion set comprises (i) a pump base to be adhered to the infusion site, and (ii) a cannula pack, consisting of a stainless steel cannula and a cannula inserter. The cannula is required to pierce through the skin, by way of introducer needle, to reach the subcutaneous tissue. 6mm and 9mm cannulae are available for Equil. The external diameter of both types of cannulae measures 0.7mm. While patients may experience swelling at the injection site, this can be managed without medication treatment.

Pump base

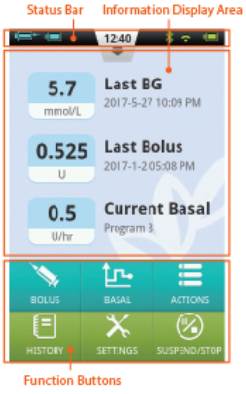


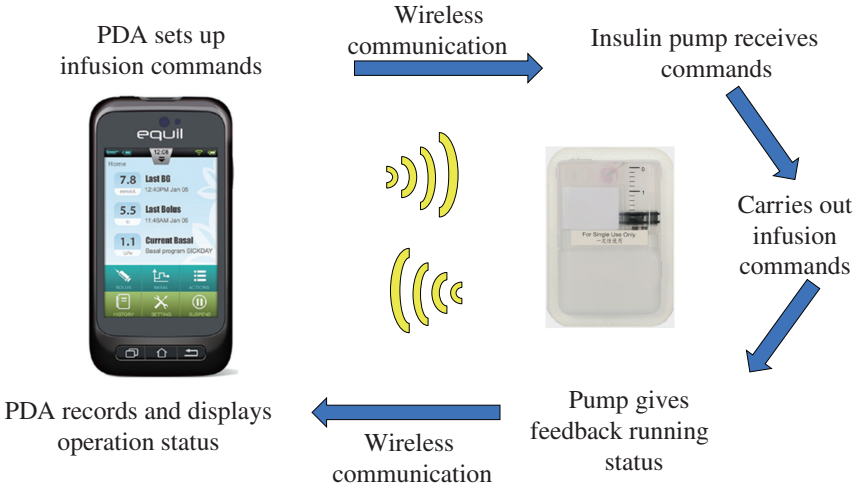
As illustrated below, users may easily presses the two opposing buttons on the cannula inserter to insert the cannula (by way of introducer needle) through the base and into the skin. The introducer needle is then disposed of using the protective sleeve.



PDA

To enjoy the full function of Equil, users must pair the patch pump with our self-designed PDA. The PDA is a handheld remote control device that wirelessly sends programs and commands to the patch pump. Users can initiate personalized basal programs and bolus deliveries using the easy-to-read touchscreen interface, and then send the desired commands wirelessly to the patch pump for execution. The PDA also wirelessly monitors the patch pump's operation and status.

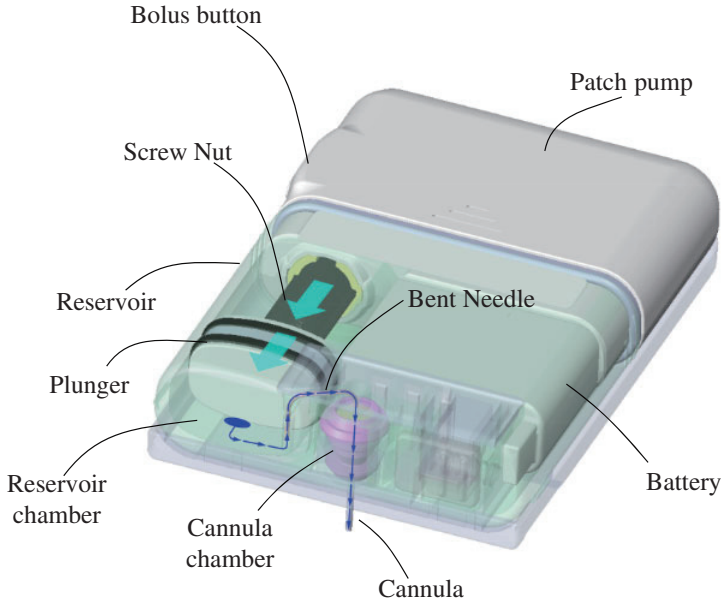




Delivery mechanism

Patients receiving multiple daily injection (**MDI**) therapy are required to inject both basal and bolus insulin manually multiple times throughout the day, using an injection device such as a syringe or a insulin pen. However, patients receiving continuous subcutaneous insulin infusion (**CSII**) therapy can avoid multiple painful injections by using an insulin pump. In addition, CSII therapy enables greater control of insulin dosages. It allows patients to pre-program varied basal rates that match their daily activity, whereas basal MDI is typically one daily shot that covers the entire day without considering daily physiological fluctuations. Under CSII therapy, bolus insulin can also be given on demand by using an insulin pump, without multiple injections per day.

As illustrated below, the fundamental delivery mechanism of Equil that helps achieve the insulin delivery through CSII, is fulfilled through a stepper motor, as well as a gearbox system with a screw-nut arrangement that transforms the rotation motion into very precise linear motion pushing the plunger. When the plunger is pushed, insulin retained in the reservoir will exit the reservoir through a bent needle and enter the cannula chamber. When the cannula chamber is full, further pressure forces the insulin to flow into the interstitial fluid. Equil uses a removable and rechargeable lithium polymer battery and provide two batteries so that the user may have one ready at all times. The battery easily meets a minimum of three-day use under normal usage conditions, with an average of 6.8 days (163 hours). The battery of Equil weighs 3.3 grams. With a fully-charged battery and full reservoir, the weight of Equil is approximately 28 grams.



Equil provides continuous insulin delivery at preset rates and can be worn for several days. Equil enables users to dose insulin precisely based on personalized needs and it is designed to fit within their normal daily routines. Insulin delivery can be changed by swiping on touchscreen of the PDA, or pressing a dedicated bolus button on the pump body without the remote control, to adapt to snacks or unexpected changes in daily routine.

Equil mimics the normally-functioning human pancreas by delivering insulin in three ways:

- basal insulin – a small, continuous infusion of background insulin delivered automatically at a programmed rate, all day and night;

- meal bolus insulin – a rapid dose of insulin delivered to counteract high blood glucose levels resulting from ingesting carbohydrates during mealtime or snacktime; and

- correction bolus insulin – an extra rapid dose of insulin to correct high blood glucose levels not associated with meals.

The greater usability and other advantages of patch insulin pumps over conventional tubed pumps have been demonstrated by the penetration of Omnipod into the insulin pump market. Though it typically requires a relatively long time to penetrate into the diabetes market given the chronic nature, Omnipod has gradually acquired market share from tubed pump and is now accounting for more than 20% of the insulin pump market in United States. According to CIC, patch insulin pump is going to further take market share from tubed pump going forward and the less penetrated markets, such as China and Europe, will witness fast growth.

Compared to the large number of tubed pumps on the market, there are only three patch insulin pumps approved for commercialization globally. Equil, being one of the commercialized patch insulin pumps, mainly will gain its market share from the tubed pumps in the near- to mid-term instead of competing with Omnipod or Accu-chek directly. Particularly, (i) Equil can be reused for four years, which is significantly longer than Omnipod-Dash System (a three-day disposable), and Accu-chek Solo (120 days). This leads to lower costs, and a similar usage life to a traditional tubed pump. In addition, Equil's rechargeable battery contributes to the waste minimization, which is a novel feature in a patch pump; (ii) Equil has a unique vibration alert in the pump itself. A vibration alert is a key differentiator in that a patient may store his or her remote PDA in a bag or purse where he cannot see, hear or sense an alert. Similarly, when wearing heavy clothing, visual and audio alerts coming from the patch pump may not be sensed by the patient. Equil is the only pump that contains a vibration alert that can be sensed by the patient underneath clothing among the commercialized patch insulin pumps. Furthermore, this feature helps to meet the IEC 60601-1-8 Alarm System standard as interpreted by the NMPA; (iii) Equil has a waterproof rating of IPx4, which allows for splashes of water from all directions. This basically means that the user may wear it while showering, which prolongs the usage life of Equil compared to other semi-disposable patch insulin pump such as Accu-chek Solo. Accu-chek Solo has a rating of

only IP22, which means that it can only withstand droplets of water from above and at a 15 degree incline. All of these features are difficult to achieve in a smaller/thinner patch pump form factor. Equil is 11.1mm thick, while Accu-chek Solo is 13mm and Omnipod-Dash System is 14.5mm. In particular, it is a significant achievement to package additional features such as a larger rechargeable battery, a vibration alert assembly, waterproof joints, and a drive system capable of injecting a small increment size in such a small package and be able to manufacture it at large scale. Furthermore, Accu-chek Solo only allows the minimum 0.01U increment for basal rates set between 0.1-5.0U/hr. Basal rates out of this range and all boluses cannot be set with this resolution. The minimum increment size for Accu-chek Solo is dependant on the basal rate or bolus size that is requested. Equil has a minimum increment size of 0.025U for all basal rates and boluses which is already sufficient for daily administration of insulin management. The comparison of Equil with its commercialized peer products is further illustrated in the chart below:

Company Product name	The Company Equil	Insulet Omnipod-Dash System	Roche Accu-check Solo
Pump	Semi-disposable	Disposable, one-time use	Semi-disposable
Duration of pump body	Four years	Three days	Four months
Weight with battery and insulin	28g	27g	29g
Battery rechargeable or not	Rechargeable battery	Non-rechargeable battery	Non-rechargeable battery
Bolus button	Yes	No	Yes
Alarms	Patch pump: LED and vibration Remote: LED, sound, and vibration	Pod: LED and sound Remote: LED and sound	Pump: sound and LED Remote: visual, sound and LED
Convenience	The pump body can be removed from the body as needed, and can be reattached	Pod cannot be reused if removed from the body	The micropump can be removed and reattached
Regulatory	Compliant with applicable NMPA regulations	Adjustments may be required to comply with applicable NMPA regulations	FDA and CE
Delivery specs	Minimum step size: 0.025U	Minimum step size: 0.050U	Minimum step size: 0.01U*
Repair or replacement warranty	√	√	√
Warranty period	Four years	Four years	Four years
Pump requires wireless remote/PDA	√	√	√
Smartphone app	×	√	×
Is the pump a hybrid closed-loop device	×	×	×
Daily cost in the U.S. (in USD)	Not approved	10	Not approved
Daily cost in the EU (in USD)	<10	10~15	20~25
Marketed Regions	China, EU	The U.S., EU	EU
Approval time	China: 2017.08 EU: 2017.06	The U.S.: 2018.06 EU: 2019.09	EU: 2018.07

* Only allow the minimum 0.01U increment for basal rates set between 0.1-0.5U/hr

Source: CIC Report, FDA, NMPA

We believe the above features make Equil attractive to patients with insulin-dependent diabetes and allow healthcare professionals to prescribe pump therapy to a broader patient group.

Market Opportunity and Competition

Diabetes is one of the most prevalent chronic diseases, which is often ill-managed due to lack of effective insulin delivery and glucose monitoring. The global prevalence of diabetes was 486.9 million people in 2019, and is expected to reach 607.6 million people in 2030, according to the CIC Report. The prevalence of diabetes in China was 118.8 million people in 2019 and is expected to reach 143.2 million people in 2030, according to the CIC Report. Insulin is one of the most widely used drugs to treat diabetes. For Type 1 diabetes treatment, it is necessary to use insulin, and there are two types of insulin therapy, MDI therapy and CSII therapy. Insulin infusion treatment is also one of the major treatment methods for Type 2 diabetes.

The market size of diabetes treatment medical devices market in China increased from US$0.3 billion in 2015 to US$0.9 billion in 2020, representing a CAGR of 21.0% from 2015 to 2020, and is expected to further increase to US$3.6 billion in 2030, representing a CAGR of 15.1% from 2020 to 2030, according to the CIC Report. The market size of diabetes treatment medical devices market globally increased from US$10.4 billion in 2015 to US$14.5 billion in 2020, representing a CAGR of 6.8% from 2015 to 2020, and is expected to further increase to US$38.0 billion in 2030, representing a CAGR of 10.1% from 2020 to 2030, according to the CIC Report.

According to the classification of insulin delivery methods, diabetes treatment devices can be mainly divided into insulin pumps, insulin pens, insulin syringes, among others. Given the multiple advantages of insulin pump, it has been more widely adopted for diabetes treatment and its market share among diabetes treatment medical devices also increased. Currently, tubed insulin pumps and tubeless patch insulin pumps are the two main types of insulin pumps. Patch insulin pumps have been shown to be significantly better than the traditional tubed insulin pump, featuring tubeless, smaller device size, greater portability and better patients' adherence to treatment regimens. The market size of insulin pumps market in China increased from US$58.1 million in 2015 to US$125.4 million in 2020, representing a CAGR of 16.6% from 2015 to 2020, and is expected to further increase to US$1.0 billion in 2030, representing a CAGR of 23.3% from 2020 to 2030, according to the CIC Report. The market size of the global insulin pumps market increased from US$4.1 billion in 2015 to US$5.6 billion in 2020, representing a CAGR of 6.6% from 2015 to 2020, and is expected to further increase to US$20.7 billion in 2030, representing a CAGR of 14.0% from 2020 to 2030, according to the CIC Report.

Equil is significantly more portable and user-friendly than the traditional tubed pump. According to the CIC Report, the penetration of patch pumps in the insulin pumps market in China remained relatively low at 3.3% in 2020 while the penetration of patch pumps in the global insulin pump market was 17.2% in 2020, indicating the significant growth potential of the patch pumps market in China. According to the CIC Report, the market size of insulin pumps in China is expected to expand at a higher growth rate (from US$125.4 million in 2020 to US$1,019.7 million in 2030, at a CAGR of 23.3%) compared to that of the diabetes treatment medical devices in China (from US$0.9 billion in 2020 to US$3.6 billion in 2030, at a CAGR of 15.1%). Furthermore, patch pumps, compared to tubed pumps, provide greater portability, safety and higher patient compliance level, are expected to experience significant growth in their market share of the insulin pump market in China from 2020 to 2030, evidenced by 3.3% to 23.2% share as percentage of total insulin pump market, according to the CIC Report.

In addition to patch pumps' relatively low penetration in China at current stage and the expected growth of the patch pump market and the overall insulin pump market in China, we believe that the market demands of our Core Product will also be driven and underpinned by the benefits that our Core Product provide to diabetes patients as well as its advantages over and affordance price as compared to its peer products. Although Equil had not been included under the national public medical insurance program in China, we believe that the retail price of Equil, being RMB28,800 per unit in China during the Track Record Period, will not affect its market demand and is affordable by the diabetes patients. According to the CIC Report, compared to traditional multiple daily injection (MDI) devices, e.g., insulin pen and insulin syringes, insulin pump provides more benefits for diabetes patients' treatment, for example, it achieves desirable blood glucose control within a shorter period of time, demonstrates lower risk of hypoglycemia and postoperative complications. In terms of affordability, insulin pumps, though incurring more upfront expenditure, have lower annual expenditure compared to MDI devices. For example, the cost of insulin usage using insulin pumps is lower. According to the CIC Report, the daily usage of insulin for insulin pumps is approximately 28.78 international units (IU) as compared to approximately 35.82 IU for MDI devices. In addition, by achieving blood glucose control within a shorter period of time and lowering risk of hypoglycemia and postoperative complications, insulin pumps accelerate patients' recovery after surgery and shorten their hospital stay thus reduce inpatient expenditure and expenditure on complication treatment.Considering the various benefits offered by insulin pumps, an increasing number of patients in China are using insulin pumps. According to the CIC Report, the penetration rate of insulin pump in China was less than 0.5% in 2020 and is expected to be around 1.5% in 2030, respectively. The price of Equil is under the average price level in the insulin pump market in China, given that the price range of the major insulin pump products in China is between RMB20,000 to RMB90,000. In particular, among the major insulin pump products in China, MiniMed of Medtronic has a price of approximately RMB40,000, with a brand market share of approximately 50% in the insulin pump market in China, and Dana Diabecare of

SOOIL has a price of approximately RMB40,000, with a brand market share of approximately 20% in the insulin pump market in China, both of which are significantly more expensive than Equil and have successfully achieved a wide market acceptance. Furthermore, as previously elaborated under "—Product Design and Technology", patch insulin pumps provide greater usability to patients, with such advantages and value demonstrated by the penetration of Omnipod into the insulin pump market; and Equil, being one of the only three patch insulin pumps in the global market approved for commercialization, is expected to achieve greater penetration at a price lower than the most widely used tubed pumps in China and gain its market share from the tubed pumps in the near- to mid-term.

According to the CIC Report, there are 17 commercialized insulin pump products in China registered with NMPA, and 34 commercialized insulin pump products registered with FDA. The following table sets forth the comparison of the insulin pump products by major manufacturers in China as of the Latest Practicable Date.

Insulin pump products by major manufacturers in China

Manufacturer	The Company	Medtronic	SOOIL	Fornia	Phray
Product name	Equil	MiniMed	DANA Diabecare	IP-101	Ph300
Approval time	2017.9	2011.12	2008.2	2003.10	2013.4
Applicable population	Adults with diabetes	Patients with diabetes who need to be treated with insulin infusion	Adults and children with diabetes	Patients with diabetes who need to be treated with insulin infusion	Patients with diabetes who need to be treated with insulin infusion
Type	Patch pump	Tubed pump	Tubed pump	Tubed pump	Tubed pump
Capacity of insulin reservoir	200U	300U	300U	300U	305U
Price/RMB	~30,000	~40,000	~40,000	~20,000	~20,000
Market share	3%	~50%	~20%	~5%	<5%

Source: CIC Report, NMPA

The following table sets forth the comparison of the insulin pump products by major manufacturers in the global market as of the Latest Practicable Date.

Insulin pump products by major manufacturers in the global market

Manufacturer	The company	Insulet	Roche	Medtronic	Tandem Diabetes Care
Product	Equil	Omnipod	Accu-Chek Solo	MiniMed(4)	t:slim
Marketed regions	China, EU	The U.S., EU	EU	EU	The U.S., EU
Applicable population	Adults with diabetes	Adults and children with diabetes	Adults with diabetes	Diabetic patients aged 7-80 years old	Diabetic patients over 6 years old
Type	Patch pump	Patch pump	Patch pump	Tubed pump	Tubed pump
Duration of pump body	Four years	Three days	Four months	Four years	Four years
Weight with battery and insulin	28g	27g	29g	N.A.	116g (Equipped with rechargeable battery)
Is the pump body reusable or not	√	×	√	√	√
Capacity of insulin reservoir	200U	200U	200U	300U	300U
Repair or replacement warranty	√	√	√	√	√
Warranty period	Four years	Four years	Four years	Four years	Four years
Pump requires wireless remote/PDA	√	√	√	×	×
Smartphone app	×	√	×	√	√
Is the pump a hybrid closed-loop device	×	×	×	√	√
Price in the U.S. (in USD)	Not approved	• Device (PDM): ~800 • Consumables:~30/set	Not approved	Not approved	~4,000
Price in EU (in USD)	• Device (PDA and pump body): 1500 ~ 2000 • Consumables: 20/set	• Device (PDM): ~400 • Consumables:~30/set	• Device (PDA and pump body): ~1700 • Consumables:~30/set	N.A.	~3,500
Daily cost(1) in the U.S. (in USD)	Not approved	10	Not approved	Not approved	N.A.
Daily cost(1) in the EU (in USD)	<10	10~15	20~25	N.A.	N.A.
Brand market share(2)	<1%	~20%	<5%	~55%	~15%

Notes:

(1) Daily cost of insulin pump = price of pump body/ duration of pump body (day) + price of consumables/duration of consumables (day). The calculation of the daily cost for the insulin pump products listed in the table above does not take into account repair cost because the respective duration of the pump body of such products is within their warranty period.

(2) Brand market share refers to the market share of the products series (i.e., not only including the specific product listed in the table above).

(3) The information unavailable from public source is indicated as "N.A."

(4) The product information takes MiniMed 780G as an example.

Source: CIC Report, FDA

The following table sets forth the major insulin pump products under development in the global market as of the Latest Practicable Date.

Major insulin pump products under development in the global market

Manufacturer	Product	Type	R&D progress	Product features
Medtronic	MiniMed780G	• Tubed pump	• Pending FDA approval	• Auto-correction every 5 mins, as needed 24/7 • Can work with Medtronic's CGM sensor Zeus to function as artificial pancreas
Tandem	t:sport mini-pump	• Tubed pump	• Pending FDA approval	• Half the size of the previous generation • No display screen
Insulet	Omnipod Horizon	• Patch pump	• Pending FDA approval	• Can be controlled by smartphone app • Conduct automated insulin delivery • Can work with CGMS to function as artificial pancreas
BD	Patch Pump for T2	• Patch pump	• Completed clinical trials	• New disposable, three-day wearable tubeless pump • Provides basal and bolus dosing • Comes with reusable handheld controller and connects to smartphone app via Bluetooth

Source: CIC Report, FDA, NIH, NMPA

It is likely that the major insulin pump products that have been commercialized or under development in the global market will enter the PRC market in the near future. There are five global major insulin pump products that entered the PRC market. Medtronic has three models of insulin pumps marketed in China—712EWS, 712WWS and 722WWS. SOOIL has two insulin pump products marketed in China—Dana 2S and Dana R.

Summary of Clinical Trial Results

We have completed a multi-center, open-label, randomized, parallel positive control, non-inferiority validation clinical trial in China to evaluate and compare the safety and efficacy of Equil with MiniMed Paradigm 712 insulin pump ("**MiniMed**"), a conventional pump, involving 152 subjects. The trial started in August 2014 and was completed in October 2015. Such completed validation clinical trial in respect of Equil in China formed a key part of the registration required by the NMPA. We conducted the trial in three sites and subjects were assigned to use Equil or MiniMed randomly on a one to one ratio. The primary efficacy indicator evaluated was the seven finger stick blood glucose values on the sixth day and the primary safety indicator evaluated was the incidence of adverse events, severity and correlation in using Equil. The seven finger stick blood glucose values refer to blood glucose values measured seven times a day, being one testing before each of the three meals, one testing two hours after each of the three meals and one testing before bed (21:00-22:00). We chose to evaluate these values, as they were shown in studies as representative values for daily glucose monitoring. The clinical trial results showed that neither the blood glucose compliance rate nor cannula success rate in the trial group (using Equil) is inferior to that of the control group (using MiniMed). We did not conduct clinical studies on the injection site reaction of Equil. According to the CIC Report, it is uncommon for the diabetes treatment medical devices companies to conduct clinical studies on the injection site reaction.

We applied following two final statistical analysis sets in this trial:

- Per-protocol population ("**PPP**"), consisting of 130 subjects that were divided into a trial group of 66 subjects and a control group of 64 subjects. PPP is a statistical analysis set that requires subjects to meet all requirements and enrollment criteria set forth in our clinical trial protocol. We excluded 22 subjects from the total 152 subjects, as they failed to meet certain requirements and enrollment criteria set forth in our clinical protocol.

- Modified intent-to-treat population ("**MITTP**"), consisting of 136 subjects that were divided into a trial group of 66 subjects and a control group of 70 subjects. MITTP is a modified statistical analysis set, where we may involve subjects who failed to meet the enrollment criteria for PPP but had valid efficacy evaluation records. In this trial, six of the 22 subjects excluded from the PPP, who had complete and valid efficacy records, were included in the MITTP, based on the determination of the principal investigator. Among these six subjects, five subjects had taken hypoglycemic drug, one case fell into the exclusion criteria and they were therefore excluded from the PPP pursuant to the clinical trial protocol.

Efficacy Results

The primary efficacy evaluation indicator in the MITTP, namely the blood glucose compliance rate of trial group, was 77.2%, higher than 57.14% of the control group. The 95% confidence interval was (4.31%, 34.53%), with its lower limit of 4.31% higher than the non-inferiority effect boundary value of -10% set by the study, and the results show that the blood glucose compliance rate of the trial group is not inferior to the control group with statistical significance (P-0.013).

The cannula success rate of the trial group is 98.51% and the control group is 100%. The 95% confidence interval was (-5.28%, 3.38%), with its lower limit of -5.28% higher than the non-inferiority effect boundary value -10% set by the study. The results show that the cannula success rate of the trial group is not inferior to the control group. The conclusions from analyzing both PPP and MITTP data were consistent.

The secondary efficacy evaluation indicators in the MITTP, namely, the difference between trial group and control group in terms of insulin pump failure rate, hypoglycemia occurrence rate, hyperglycemia occurrence rate, total insulin dosage, daily average blood sugar and blood fluctuation were not statistically significant. The conclusions from analyzing both PPP and MITTP data were consistent.

Safety Results

A total of 27 subjects in this trial had a critical blood sugar event (hyperglycemia and hypoglycemia symptoms that occurred), in which 14.47% occurred in the test group, and 21.05% occurred in the control group. A total of 78 cases of adverse events (adverse events other than critical blood sugar events, such as dizziness, constipation and bacterial infection) occurred, in which 56.58% occurred in the test group, and 46.05% occurred in the control group. A total of 3 cases of serious adverse events occurred and all of them were in the control group. There was no statistically significant difference in critical blood glucose value, incidence of adverse events (including serious adverse events), severity, and device correlation between the two groups.

Research and Development Plans

As of April 30, 2021, we incurred R&D expenses of RMB148.6 million on our Core Product primarily in connection with the preclinical studies and clinical trials in China for our Core Product. We incurred R&D expenses of RMB52.7 million on our Core Product before it was commercialized and incurred R&D expenses of RMB95.9 million for its product improvement and indication expansion to children and adolescents' use after it was commericalized. Our R&D in relation to our Core Product has been a continuing effort, even after we received the CE marking in Europe in June 2017, and the marketing approval by the NMPA, for adult use, in China in September 2017. Since the commercialization of Equil, we have been constantly reviewing its performance and customer experience based on feedback collected and making improvements to its functions, such as signal processing, display of PDA touch screen and recharge function.

In 2019, 2020 and the four months ended April 30, 2021, we incurred research and development expenses of RMB25.4 million, RMB39.7 million and RMB3.1 million for our Core Product, respectively, primarily for the expansion of the use of Equil to children and adolescents and the product improvement of our Core Product which will improve the functions of Equil, such as its product design and performance stability, both for adult use and its expansion of use to children and adolescents.

Expansion to Use by Children and Adolescents

We plan to expand the Core Product's indication for children and adolescents' use due to the following reasons:

- ***The strong demand and substantial long-run per patient expenditure of children and adolescent diabetic patients.*** According to IDF, and Treatment Guidelines for Type 1 Diabetes China 2011, Type 1 diabetes patients account for approximately 5-10% of the total diabetes population. According to IDF, approximately 50% of children and adolescent diabetic patients are Type 1 diabetes patients. It is necessary for Type 1 diabetes patients to use insulin, and insulin pumps are CSII devices for controlling insulin infusion in the treatment of Type 1 diabetes patients, as well as the treatment of Type 2 diabetes patients that require intensive insulin therapy. In light of the foregoing, children and adolescent diabetic patients, especially those with Type 1 diabetes, have a strong demand for insulin therapy medical devices. Given that Type 1 diabetes is a life long condition that needs lifetime monitoring and management, the long-run per patient expenditure of children and adolescents diabetic patient group is expected to be substantially high.

- ***Significant growth potential after achieving market acceptance.*** Compared to tubed pumps, patch pumps, as the new-generation of insulin pump, are more portable, more discreet, enabling higher patient compliance level and lower risk of clogging, and therefore are expected to gain market acceptance and capture more market opportunities in China. Though it takes time for us to educate the patient group and medical institutions on the benefits of patch pumps and change habits of users using tubed pumps or any MDI therapy device, we believe that in the long-run, we are well-positioned to strengthen first-mover advantages and establish the brand recognitions among insulin therapy patients in China to capture the future growth opportunities.

We had been engaged in the research and development on the expansion of the use of Equil to children and adolescents (aged 3 to 18 years old) since the second quarter of 2019. Currently, we are preparing for a pivotal multi-center, open-label, randomized, cross-over, non-inferiority validation clinical trial in China to expand the use of Equil to children and adolescents (aged 3 to 18 years old) with diabetes. As of the Latest Practicable Date, we had determined nine principal investigators and engaged three SMOs. The headquarters of SMOs are located in Beijing, Zhejiang and Jiangsu and have a total of approximately 2,000 R&D staff. The total service fees payable to these three SMOs, which are estimated based on our clinical trial plan and shall be subject to adjustment based on the amounts these SMOs have actually incurred, are approximately RMB0.3 million. As of the Latest Practicable Date, we had finalized the clinical trial protocol design, completed the ethics committee review, and obtained approvals by the target hospitals to perform the clinical trial. We are currently in the process of executing the agreements with target hospitals to perform the clinical trials and providing relevant trainings to physicians and nurses, which we expect to take two months.

The test subjects will be children and adolescents (aged 3 to 18 years old) with diabetes. We plan to enroll 74 subjects at 10 different clinical sites. We had started the preparation of patients' enrollment since May 2021. The leading institution started to enroll patients in August 2021 and we expect the patient enrollment process to take three to four months. The primary efficacy indicator to be evaluated will be mean blood glucose and the primary safety indicator to be evaluated will be incidence of adverse events, severity and correlation in using different devices. We expect to complete the registrational clinical trial in China and submit the registration application to the NMPA in the first half of 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EQUIL, INCLUDING THE EXPANSION OF THE INDICATION OF EQUIL FOR CHILDREN AND ADOLESCENTS' USE SUCCESSFULLY.

Material Communication with NMPA

With respect to the registration application of Equil indicated for adult use, we had two rounds of official communications with the NMPA through scheduled in-person conferences for technical review. We also had one round of written communication with the NMPA to supplement additional materials for purposes of the registration application. We had no material difficulty in addressing comments of the NMPA during these communications.

With respect to registration of Equil for children and adolescents' use, we have consulted with the provincial counterpart of the NMPA, which has confirmed that (i) we can register children and adolescents' use as an expansion of the indications stated in the Class III registration certificate of Equil we currently hold by modifying such certificate, and we may also at our discretion apply for a new registration certificate for such indication expansion; (ii) a clinical trial is required by the NMPA for the purposes of seeking its approval of such indication expansion and modification or a new registration certificate application; and (iii) the modified or new registration certificate will form the basis of the NMPA and its local counterpart's future regulation over such indication expansion. Accordingly, the clinical trial in respect of the expansion of indication of Equil for children and adolescents' use is required by NMPA.

We consider the provincial counterpart of the NMPA is the competent authority for matters in relation to our Core Product and other pipeline product candidates as (i) according to the Administrative Measures on the Registration of Medical Devices, promulgated by the NMPA on July 30, 2014, the provincial NMPA is responsible for supervising and administering the registration and record-filing of medical devices in its administrative division, and shall organize inspections and timely submit relevant information to the NMPA; and (ii) the products we produce and sell in China are mainly Class II and Class III medical devices. Pursuant to the Regulation on the Supervision and Administration of Medical Devices and based on our consultation with the Center of Medical Device Evaluation of Zhejiang Medical Products Administration ("**ZJMPA**"), the authorized officer confirmed that the ZJMPA is the competent authority for the approval and registration of Class II medical devices in Zhejiang Province; and although the approval and registration of Class III medical devices is supervised by the

NMPA, the authorized officer confirmed that all medical device manufacturers located within Zhejiang Province are supervised and managed by the ZJMPA and that the ZJMPA has authority to interpret the Regulation on the Supervision and Administration of Medical Devices and other relevant regulations.

In accordance with the requirements under Article 13 of the Regulations on the Supervision and Administration of Medical Devices, Class III medical devices are subject to registration management. In the case of any substantial changes in (i) the design, (ii) raw materials, (iii) production process, (iv) indication of use, or (v) method of use, manufacturers may submit an application for modification of original registration certificate in accordance with Article 21 of the Regulations on the Supervision and Administration of Medical Devices. On such basis, and as confirmed by the regulatory authority in the consultation described above, we are allowed to register children and adolescents' use as an expansion of the indications stated in the Class III registration certificate of Equil we currently hold by modifying such certificate, and we may also at our discretion apply for a new registration certificate for such indication expansion.

In practice, to apply for a new registration certificate of a medical device with an intended use in both adult and pediatric groups of population, applicants may be required to complete the validation clinical trial for use both groups. In addition, given that the regulatory authority has reviewed and evaluated the major efficacy and safety profile of the original medical device in adult use, an application to modify the original registration certification is acceptable by the regulatory authority and avoid the duplicative work required to apply for a completely new registration. As such, we will perform the clinical trial required by the regulatory authority and apply for the modification of the indications stated in the Class III medical device registration certificate of Equil to include the additional indication for children and adolescents' use.

In July 2020, we communicated with the NMPA regarding the clinical trial for such indication expansion, and then filed the clinical trial record with the local counterpart of the NMPA.

Pursuant to the Regulation on the Supervision and Administration of Medical Devices, which was recently revised by the State Council and came into effect on June 1, 2021, and the Good Clinical Practice for Medical Device Trials, which was came into effect on June 1, 2016, applicants shall file the clinical trial protocol with relevant local counterpart of the NMPA before launching the clinical trials. Only applicants, whose medical device pending registration is listed in Class III Medical Device Catalog Subject to Approval for Clinical Trials, shall obtain approval of trial design from the NMPA. Such catalog primarily lists medical devices with higher risk to human body, such as implantable devices. As advised by our PRC Legal Advisor and confirmed by our consultation with the provincial counterpart of the NMPA, patch insulin pump system is not listed in the such catalog, and therefore we are not required to obtain approval of our trial design from the NMPA.

Other than the above, we have not had any material regulatory communications with the NMPA for the development of Equil, and we are not aware of any material concern from the NMPA in connection with Equil. As of the Latest Practicable Date, no material adverse change had occurred with respect to our marketing approval of Equil.

Post-market Studies

We plan to carry out post-market studies of Equil in the United States and Europe to collect more clinical evidence of Equil's efficacy and safety profile. We expect to commence the post-market studies in Europe and the United States in 2022 and 2023, respectively, and complete such studies in the respective jurisdictions in 2023 and 2024.

Second-Generation Patch Insulin Pump System

Our second-generation patch insulin pump system will be built on the technology infrastructures of Equil, including the proprietary drive system, sensors, software, embedded firmware, algorithm, architecture and accessories. It will feature smaller size, improved waterproof performance, more convenient battery charging mechanism, better adaptability to insulin reservoirs with a capacity of up to 300U. We have completed the feasibility and market research in the first quarter of 2021.

We have been working on the design of our second-generation patch insulin pump system since March 2021, which is expected to take three months. As of the date hereof, we had completed the mechanical design of the patch pump architecture and hardware on the basis of Equil. The architecture and hardware of the second-generation pump will be smaller in size but adaptable to insulin reservoir with larger capacity. In addition, we improved our techniques and built in additional sealing structures between the pump and the insulin reservoir of Equil to achieve an IPX8 waterproof rating (i.e., to withstand continuous immersion in water). Furthermore, we modified the cannula and cannula inserter of Equil to improve the ease of use of our second-generation patch insulin pump system. Additionally, the second-generation patch insulin pump system will expand the intended use of Equil. It is designed to embed control algorithms that function to continuously collect blood glucose readings from the AiDEX CGMS, our CGMS products.

We are currently in the process of designing electronics and control systems that accommodate to the space limitation set by the smaller chassis of the patch pump. We anticipate the design process to take three months. The engineering verification of our second-generation patch insulin pump system will be primarily focused on testing and verifying the design inputs and system technical specifications, including testing of insulin delivery accuracy, electro-magnetic compatibility, biocompatibility and usability, among others. We anticipate to complete the engineering verification in the second half of 2021. Thereafter, we plan to initiate communications with the NMPA for the next steps, including seeking the NMPA certification on the eligibility of Special Approval Procedure for Innovative Medical Devices, as well as submitting samples to the local counterpart of NMPA for the official type testing. We will also communicate with the NMPA and clinical experts with

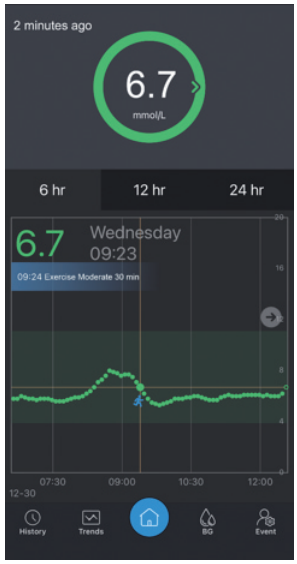
respect to the clinical trial design. We plan to initiate the clinical trial in the first half of 2022. We expect to complete the registrational clinical trial and submit the registration application to the NMPA in the first half of 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR SECOND-GENERATION PATCH INSULIN PUMP SYSTEM SUCCESSFULLY.

AiDEX CGMS

AiDEX CGMS is designed to gather information about glucose levels every few minutes, allowing the user to see a graph of glucose levels rather than just a single measurement snapshot at a given point in time. Continuous glucose monitoring is potentially useful to anyone with diabetes, and is especially useful for patients undergoing MDI or receiving the CSII therapy. AiDEX G7, our first AiDEX CGMS, primarily focuses on the clinical needs of patients with Type 1 diabetes and severe Type 2 diabetes who need to closely monitor their blood glucose levels. The user of AiDEX G7 inserts a sensor that measures the glucose level of subcutaneous interstitial fluid. The sensor connects to a transmitter that beams the glucose data wirelessly to a receiver, which can be either a dedicated handheld device or a mobile phone with the relevant application installed. The sensor of AiDEX G7 can be worn for 14 days and then replaced with a new one.

As illustrated below, the real-time glucose level graph displayed by our CGMS provides detailed information on the user's glucose fluctuation. The user can track glucose levels during specific parts of a daily routine, such as before or after mealtimes, during sleep, or during exercise. This can give the user a better awareness of his or her body's needs throughout the day.



AiDEX G7 received CE marking in Europe in September 2020. We started to commercialize AiDEX G7 in Europe in March 2021. The selling price of AiDEX G7 per unit in Europe ranges from $23 to $30. We completed a clinical trial for AiDEX G7 in China in May 2020 and the NMPA accepted our registration application in the first quarter of 2021.

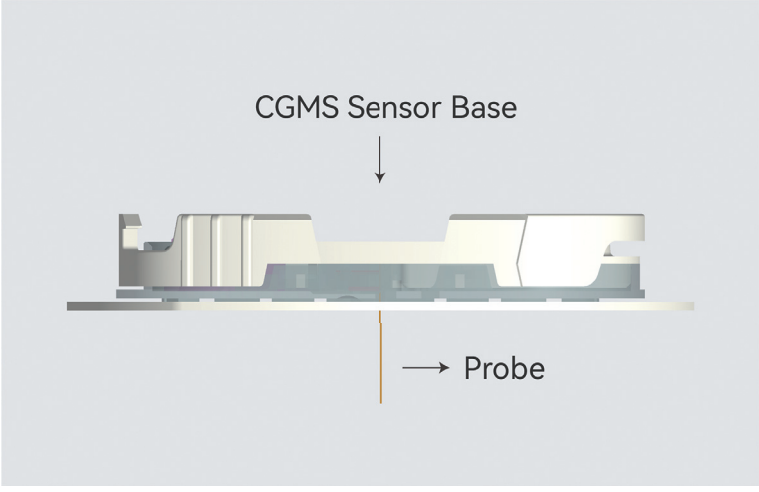
Product Design and Technology

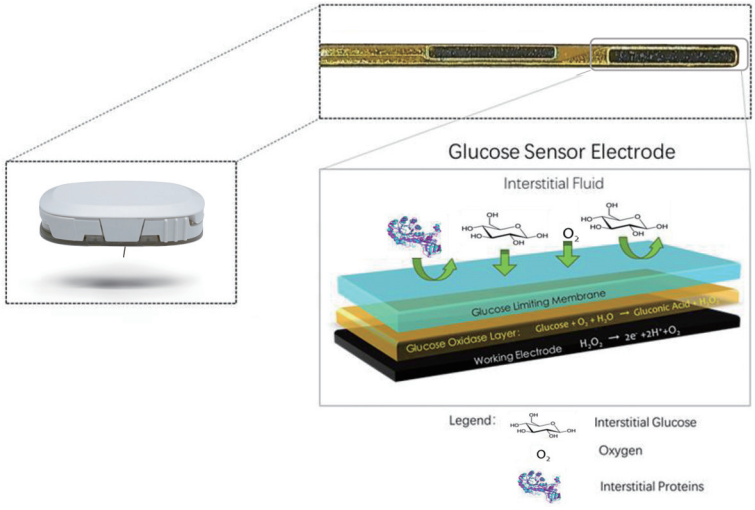
AiDEX G7 primarily consists of three components: a tiny disposable 14-day glucose sensor that is inserted subcutaneously by the user; a reusable transmitter that receives, assesses and relays data from the sensor; and a reusable receiver that receives data from the transmitter and provides real-time glucose readings, alerts and other data. All disposable components are single use and are provided in sterilized packaging. All of these components work together to provide glucose readings, trends and alerts to the user's mobile device in real time.

Long-lasting disposable glucose sensor

The glucose sensor is intended to be inserted under the skin, on the upper arm or abdomen in an almost painless way to measure the glucose levels in the interstitial fluid. Users will use a non-reusable sensor applicator to facilitate the insertion of the sensor. These glucose data are collected by the transmitter and then wirelessly communicated to a PDA or a mobile phone installed with the application.

The glucose sensor consists of a small flexible sensing probe, and a sensor base with adhesive patch that ensures the sensor securely adheres to the skin and connected with the transmitter. The sensing probe has a working electrode that measures the interstitial fluid glucose level via glucose oxidase-mediated electrochemical reactions; it also has a dedicated interference detection electrode which ensures elimination of the noise signals from interfering substances such as acetaminophen or ascorbic acid.





Smart reusable transmitter

The transmitter of AiDEX G7 is powered by a disposable battery built into the sensor and does not need to be recharged. After the transmitter is snapped onto the sensor, the electrochemical signal generated by the sensor will be relayed to the transmitter. The transmitter uses current/impedance dual-mode monitoring technology to automatically and intelligently correct blood glucose calculations. The transmitter generates a blood glucose reading every five minutes and sends a signal via Bluetooth. The information from the transmitter is also transmitted for display to the user's mobile device, leveraging Bluetooth low energy ("**BLE**") technology.

Receiver

Users can set up, control or read data from AiDEX CGMS either through a mobile phone installed with relevant iOS or Android applications or a PDA. We design these mobile applications and the PDA.

Mobile phone (installed with application)

Our mobile app communicates with the transmitter through BLE and obtains blood glucose data from the transmitter. The application installed on the user's mobile phone can display current blood glucose readings and trends in a user-friendly fashion. The application can also display statistical data, such as the user's aggregated glucose profiles, average blood glucose level in the last seven days, 14 days, or 30 days, the frequency and duration of high and low blood glucose events. The application can alert users with sounds and vibrations, when AiDEX CGMS detects high/low blood glucose and rapid blood glucose rises/falls. Users can also calibrate the transmitter through the application and record their exercise, diet, medication and insulin infusions. The user can opt to share his or her glucose data with others, such as family members or healthcare providers.

PDA

Users can use a PDA as an alternative, which provides similar functions as the mobile application, except that certain ancillary functions, such as daily activity record and cloud storage, are not available. However, the PDA has a customized and dedicated system that has been thoroughly tested alongside the AiDEX CGMS glucose sensor and the transmitter, which is expected to provide more predictable performance than the mobile application.

Market Opportunity and Competition

Diabetes monitoring medical devices can be classified as traditional BGMS, CGMS and others, such as HbA1C and ketones testing. For the prevalence of diabetes in China and globally, see "—Equil – Core Product—Market Opportunity and Competition." The market size of diabetes monitoring medical devices market in China increased from US$0.5 billion in 2015 to US$1.3 billion in 2020, representing a CAGR of 22.7% from 2015 to 2020, and is expected to further increase to US$6.1 billion in 2030, representing a CAGR of 16.8% from 2020 to 2030, according to the CIC Report. The market size of the global diabetes monitoring medical devices market increased from US$17.4 billion in 2015 to US$26.8 billion in 2020, representing a CAGR of 9.0% from 2015 to 2020, and is expected to further increase to US$73.8 billion in 2030, representing a CAGR of 10.7% from 2020 to 2030, according to the CIC Report. For advantages of CGMS over traditional BGMS, see "Industry Overview—Diabetes Monitoring Medical Devices Market—CGMS Market."

The CGMS market is fast-growing and CGMS products are witnessing a wider acceptance. Moreover, with people's increasing healthcare awareness, the penetration rate for CGMS is expected to experience a significant growth in the future. In China, for Type 1 diabetes, the penetration rate of CGMS was 0.2% in 2015 and 6.9% in 2020 and is expected to further increase to 38.0% in 2030; for Type 2 diabetes, the penetration rate of CGMS was 1.1% in 2020 and is expected to further increase to 13.4% in 2030, according to the CIC Report.

Due to the advantages of CGMS compared with traditional BGMS and the rising acceptance of patients, the market size of the CGMS market in China increased from US$8.78 million in 2015 to US$0.1 billion in 2020, representing a CAGR of 73.2% from 2015 to 2020, and is expected to increase to US$2.6 billion in 2030, representing a CAGR of 34.0% from 2020 to 2030, according to the CIC Report. The market size of the global CGMS market increased from US$1.7 billion in 2015 to US$5.7 billion in 2020, representing a CAGR of 28.2% from 2015 to 2020, and is expected to increase to US$36.5 billion in 2030, representing a CAGR of 20.3% from 2020 to 2030, according to the CIC Report. According to the CIC Report, there were a total of 11 commercialized CGMS products in China registered with NMPA and 12 commercialized CGMS products registered with FDA as of the Latest Practicable Date. The following tables set forth the major marketed CGMS products in the global market as of the Latest Practicable Date.

Global major marketed CGMS products

Performance	The Company's AiDEX G7	Abbott Freestyle Libre Pro Flash	Medtronic Guardian	Dexcom G6
Calibration	Calibration-free	Calibration-free	Twice per day	Calibration-free
Usage Time	14 days	14 days	7 days	10 days
Startup Time	1 hour	1 hour	2 hours	2 hours
Transmitter Life	4 years	1 year (sensor integration)	1 year	3 months
Frequency of Readings	5 min (realtime)	15 min (retrospective)	5 min (realtime)	5 min (realtime)
Alarm Functions	Realtime high and low glucose alarm	None	Realtime high and low glucose alarm	Realtime high and low glucose alarm
Built in Traditional Meter	Included	Included	None	None
Accuracy (MARD)(1)	9.1%	12.1%	9.1-10.6%	9.0%
Launching Market	EU	The U.S., EU, China	The U.S., EU, China	The U.S., EU
Cost in the U.S	N.A.	~US$150 per month	~US$300 per month	~US$300 per month
Cost in the E.U.	N.A.	~GBP90 per month	~GBP200 per month	~GBP160 per month
Cost in China	N.A.	~RMB1,000 per month	~RMB3,100 per month	N.A
Brand Market Share(2)	<1%	>50%	<10%	>30%
Picture				

Note:

(1) MARD refers to the mean absolute relative difference, which is the average value of the absolute error between the CGMS detection value and the referenced value. The lower the value, the higher the accuracy.

(2) Brand market share refers to the market share of the products series, not only including the specific product listed in the table.

Source: CIC Report

The following tables set forth the major CGMS products under development in the global market as of the Latest Practicable Date.

Global major CGMS products under development

Manufacturer	Product	R&D progress	Product Features
The Company	AiDEX G7	Pending NMPA approval	Calibration-free Real-time monitoring Usage time: 14 days
Dexcom	G7	Pending FDA approval	Calibration-free Smaller than G6 Usage time: 10 days
Abbott	Libre 3	Pending FDA approval	Calibration-free Real-time monitoring Smaller than Libre 2 Usage time: 14 days
Senseonics	Eversense 180-day	Pending FDA approval	1 time per day calibration Real-time monitoring Usage time: 180 days
Medtronic	Zeus	Completed pivotal trial	Need calibration on the first day Usage time: 7 days
WaveForm Diabetes	Cascade	In clinical trial	1 time per day calibration Real-time data monitoring Usage time: 14 days

Source: CIC Report, FDA, NMPA, NIH

It is likely that the major CGMS products that have been commercialized or under development in the global market will enter the PRC market in the near future. There are global major CGMS products that entered the PRC market. Abbott's Freestyle Libre CGMS obtained NMPA Class III approval in 2016, and Medtronic's Guardian Connect CGMS obtained NMPA Class III approval in 2020.

Summary of Clinical Trial Results

From July 2019 to May 2020, we conducted a pivotal, multi-center, randomized, paired-design validation clinical trial in China. All subjects who participated in this trial were divided into two groups: the outpatient group and the inpatient group. Both groups wore AiDEX G7 for 14 days continuously. All subjects were randomly assigned to participate in an eight-hour supervised observation session where blood samples were collected every 15 minutes. We enrolled 120 subjects, with 120 subjects included in the full analysis set ("**FAS**"), 90 subjects included in the per-protocol set ("**PPS**"), and 120 subjects included in the safety set ("**SS**").

The FAS consisted of subjects who executed the informed consent and used the trial device at least once and generated evaluation data. The PPS consisted of subjects who fully complied with the requirement and did not fall into any exclusion criteria set forth in our clinical trial protocol. The SS consisted of subjects who used the trial device at least once and generated safety data.

Among the 30 subjects excluded from the PPS, seven subjects voluntarily dropped out of the clinical trial due to personal reasons or deemed inappropriate to continue the trial, 17 subjects were excluded due to incomplete evaluation data, and six subjects were excluded because they failed to comply with certain requirements of clinical trial protocol, such as failure to collect evaluation data within the set timeframe.

The primary efficacy evaluation indicators include percent of results within 20% of the referenced value, mean absolute relative difference ("**MARD**") compared with referenced value, among others. The secondary efficacy evaluation indicators include high and low glucose alert performance, glucose sensor stability, glucose sensor use life and glucose sensor usability. In order to evaluate efficacy indicators, investigators compared the blood glucose values measured by AiDEX G7 with the venous blood glucose values measured by Yellow Spring Instrument (YSI) as references. YSI is the recognized standard for laboratory analysis of blood glucose. For safety evaluation, we recorded all adverse events associated with the use of our device, and evaluated the adverse event occurrence rate and the percentage correlation.

The trial device has been proven to meet the primary and secondary efficacy indicators, and safety. Therefore, this trial has verified that AiDEX G7 can be used safely and effectively on diabetes patients older than 14 years old in both inpatient and outpatient settings for continuously or periodically monitoring tissue fluid glucose levels and identifying potential hypoglycemia or hyperglycemia events.

Efficacy Results

(1) Primary efficacy indicators

The precision of the blood glucose values measured by AiDEX G7 to paired YSI values was assessed by calculating the percentage of blood glucose values measured by AiDEX G7 that were within 20mg/dL or 20% of the paired YSI reference glucose values, or 20/20% agreement with YSI reference. Point estimate of the overall 20/20% agreement rate with YSI reference of AiDEX G7 was no less than 95.46%, with lower boundary of the 95% confidence interval at 94.29%. Both values were higher than the target point estimate (>65%) and lower boundary of 95% confidence interval (>60%) set by the study as a requirement by the NMPA.

In our study, accuracy was measured by comparing the mean absolute relative difference ("**MARD**"), which measures the average percent disagreement between the AiDEX G7 and YSI reference. MARD indicates the average percentage disagreement between AiDEX G7 and YSI reference. The point estimate of the overall MARD of AiDEX G7 compared with YSI reference was no greater than 9.55%, with 95% confidence interval of 3.99% - 15.12%. Both values were better than the target point estimate (<18%) and upper boundary of 95% confidence interval (<20%) set by the study as a requirement by the NMPA.

(2) Secondary efficacy indicators

The high glucose alert success rate, high glucose detection success rate, low glucose alert success rate and low glucose detection success rate of AiDEX G7 were 90.57%, 95.92%, 97.37% and 86.67%, respectively. The glucose sensor stability was evaluated on different body parts and on the second, sixth to eighth, and fourteenth day after the enrollment, with all 20/20% agreement rates with YSI reference higher than the point estimate set by the study. Percentage of sensors meeting 14 days of usage time ranges from 97.78% to 100.00%. Subjects participated in this trial were overall satisfied with the use of AiDEX G7.

Safety Results

During the clinical trial, we observed a total of 60 adverse events, including one severe adverse event (in the inpatient group) unrelated to the use of the CGMS being evaluated. The adverse events that are related to the use of CGMS include blood seepage, pain after insertion, skin irritation and slight redness, which all of were eliminated after mitigation.

In April 2019, we filed the trial protocol for AiDEX G7 with the local counterpart of the NMPA. We commenced the pivotal clinical trial for AiDEX G7 in China in July 2019 and completed the clinical trial in May 2020.

Material Communication with Competent Authorities

In February 2020, we submitted written materials to the NMPA for evaluating the eligibility of AiDEX G7 to follow the Special Approval Procedures of Innovative Devices promulgated by the NMPA. In May 2020, AiDEX G7 passed the evaluation of the NMPA and was certified to be eligible to follow the Special Approval Procedures of Innovative Devices promulgated by the NMPA. In February 2021, we had another official communication with the NMPA. Due to the outbreak of COVID-19, the NMPA organized such communication in the form of an online conference. During the communication, the NMPA and our Company mainly discussed about product registration application in respect of AiDEX G7. Following such communication, we submitted our registration application and the NMPA accepted such registration application in the first quarter of 2021. Other than the above, we have not had any material regulatory communications with the NMPA for AiDEX G7. We expect to obtain the marketing approval from the NMPA in the third quarter of 2021.

For the purposes of commercializing our AiDEX G7 in the U.S., we are preparing for the 510(k) premarket submission. In this connection, we are not required to conduct a validation clinical trial in the U.S., while we are required to demonstrate that AiDEX G7 is at least as safe and effective as, that is, substantially equivalent to, an existing legally marketed device, or predicate device. In March 2020, we made a pre-submission to request formal feedback from the FDA on the contemplated 510(k) premarket submission of our AiDEX G7. In such communication, we primarily discussed with the FDA about the scope of clinical data required for such submission. Pursuant to the FDA's response, we should collect adequate performance data from the adult population and provide that the performance of our device in the pediatric

population should be similar to the adult performance. As such, the results of our clinical trial completed in May 2020 in China to validate the intended use of AiDEX G7 among adults will form a key part of our future 510(k) premarket submission. Results of our clinical trials among pediatric population, when available, will also form a part of such submission.

Expansion to Use by Children and Adolescents

We plan to conduct a clinical trial to expand the use of AiDEX G7 to children and adolescents with diabetes in the second half of 2021. The test subjects will include children and adolescents (aged 3 to 18 years old) with diabetes and we plan to enroll 60 subjects at three different clinical sites. We are responsible for the trial design and trial report and will engage CROs to coordinate the trial. The primary efficacy indicator to be evaluated will be the CGMS accuracy comparing to YSI reference. We expect to receive the approval for the clinical trial and complete the patient enrollment in the second half of 2021.

AiDEX X

We are in the process developing AiDEX X, a CGMS that complements AiDEX G7 and cater to non-intensive diabetics, pre-diabetics, and health-aware non-diabetic users. AiDEX X will balance the need of a reasonable accuracy in blood glucose readings and meet the requirements of the FDA's iCGM classification of Class II medical devices with price, convenience and comfort. AiDEX X will feature the use of new glucose sensing technology and reduced size, aseptic packaging, and usage time of no less than 15 days.

We have completed product feasibility analysis, sensing technology iteration, chip development and ID design. We plan to complete product prototype trial production and production process optimization in the second half of 2021, and complete medical device registration type testing in 2021. We expect to complete the clinical trial and submit the registration application to the NMPA in the second half of 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND/OR MARKET AIDEX G7, INCLUDING THE EXPANSION OF THE INDICATION OF AIDEX G7 FOR CHILDREN AND ADOLESCENTS' USE AND AIDEX X SUCCESSFULLY.

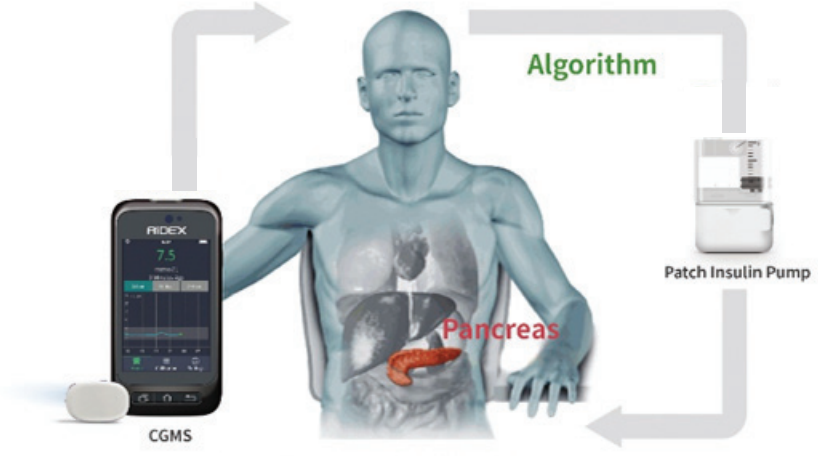
PanCares — Artificial Pancreas

PanCares, our artificial pancreas, is a combination of the second-generation patch insulin pump system embedded with control algorithms and the AiDEX CGMS. It offers patients a closed loop diabetes management solution by coupling our CGMS and our patch insulin pump via control algorithms.

We plan to develop and commercialize our artificial pancreas indicated for use of adult patients, and further expand such indication to children and adolescents at a later stage. We have completed a market and feasibility research in the first quarter of 2021, and expect to complete the engineering verification of our artificial pancreas in the first half of 2022. We are required to conduct a clinical trial for obtaining the NMPA marketing approval. We expect to complete the ethics committee review, obtain approvals by participating hospitals, initiate the clinical trial in 2022 and register in China, the U.S. and the EU in 2023.

Product Design and Technology

The artificial pancreas is an integrated diabetes management medical device that tracks blood glucose levels using a continuous glucose monitor and automatically delivers the insulin when needed using an insulin pump according to its control algorithm. An artificial pancreas works in a similar way as the real human pancreas – it maintains a continuous, variable basal insulin delivery (which the delivery rate is higher when blood glucose is high, and delivery is less or even completely stopped when blood glucose is low).



The control algorithm for an artificial pancreas is essentially a feedback loop, which functions to continuously collect blood glucose readings from the CGMS and insulin delivery history from the insulin pump, then calculate the residual insulin on board values and predict the change in the blood glucose. Based on such information and the glucose target range set by the user, it calculates how much insulin should be delivered in the next time window and send the command to the pump for execution.

Our artificial pancreas control algorithm utilizes a hybrid of the classical proportional-integral-derivative approach and the new model-based prediction control approach to provide best-in-class performance. Besides current and historical blood glucose values and insulin delivery history, our artificial pancreas is also designed to consider patient-specific parameters to fine-tune the output. Up to the date hereof, we have been conducting vigorous simulation testing, which has yielded satisfactory results. Meanwhile, we are in the process of developing the decision-making algorithm around the closed loop control algorithm to ensure the safety of the integrated system under even the most extreme circumstances. An integrated system embedded closed loop algorithm, when available, will also be subject to further testing and verifications.

In addition, we plan to integrate cloud-based data analysis and AI technologies to our artificial pancreas, for the purposes of data mining and algorithm optimization, which will allow every user to enjoy a customized, safe and worry-free using experience.

Market Opportunity and Competition

According to the guidance entitled the Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems issued by the FDA on November 9, 2012, the Artificial Pancreas Device System is a system of devices that closely mimics the glucose regulating function of a healthy pancreas. The FDA does not include glucagon delivery in their description of the Artificial Pancreas Device System. Artificial pancreas device consists of three important components: (1) a glucose sensor/monitor, (2) an insulin pump to store and deliver insulin, and (3) a control algorithm to compute the amount of insulin to be delivered and communicated between the sensor and the pump. Compared to existing diabetes management medical devices, the artificial pancreas device connects the treatment and monitoring functions of diabetes in a series, while the feedback regulation mechanism of a human pancreas is simulated by the closed loop control algorithm to realize the automation of treatment and monitoring, i.e., reducing high blood glucose levels (hyperglycemia) and minimizing the incidence of low blood glucose (hypoglycemia) with little to no input from the patient. As the awareness of the advantages of artificial pancreas grows, the market size of the artificial pancreas device market in China is projected to reach US$30.8 million in 2023 and approach to US$488.4 million by 2030. The market size of the global pancreas device market increased from US$522.4 million in 2017 to US$1,053.9 million in 2020, representing a CAGR of 26.4% from 2017 to 2020, and is expected to further increase to US$6,735.3 million, representing a CAGR of 20.4% from 2020 to 2030.

According to the CIC Report, there was no artificial pancreas device marketed in China as of the Latest Practicable Date. The table below sets forth the major artificial pancreas products in the global artificial pancreas device market as of the Latest Practicable Date.

Major players in global artificial pancreas device market

Medtronic

Product	MiniMed 770G
FDA approved date	Sep-2020
Components	Calibration required CGMS + tubed pump
FDA approved patient group	≥2 years old patients with Type 1 diabetes
Auto Mode	✓
Basal Automation	✓
Bolus Automation*	✗
Price in the U.S. (USD)	~8,000

Tandem

Dexcom

Product	Control-IQ hybrid closed loop
FDA approved date	Dec-2019
Components	Calibration-free CGMS + tubed pump
FDA approved patient group	≥6 years old patients with Type 1 diabetes
Auto Mode	✓
Basal Automation	✓
Bolus Automation	✓
Price in the U.S. (USD)	~4,000 (Pump only)

Note:

* MiniMed 770G will recommend a correction bolus, but need to manually accept.

Source: CIC Report, FDA

According to the CIC Report, our artificial pancreas device is expected to become the world's first closed loop solution that integrates the self-developed calibration-free CGMS and patch insulin pump system.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PANCARES SUCCESSFULLY.

IVD Devices

BGMS Products

Blood glucose monitoring system, or BGMS, is a main type of diabetes monitoring medical device and has been used for years. BGMS usually collects blood drawn from the fingertip and uses disposable test strips to place into and reload the blood glucose meter so as to obtain single-shot blood glucose results. Test strips are supplied by the glucometer manufacturer and are generally device-specific. We had started to commercialize BGMS products in China and Europe since December 2013 and February 2016, respectively. We obtained the 510(k) clearance for our BGMS from the FDA in September 2020. As of the Latest Practicable Date, we had not commercialized our BGMS in the United States. As of the Latest Practicable Date, we had developed and commercialized 15 types of blood glucose meters and seven types of test strips in China. In addition, our BGMS products had received marketing approvals in major markets overseas, including the U.S. and the EU. As of the Latest Practicable Date, we had developed and commercialized 12 types of blood glucose meters and six types of test strips overseas.

Exactive Pro—Glucose, Ketone, Uric Acid Monitory System

We are leveraging our accumulated experience and know-how in BGMS products to develop Exactive Pro, which is designed to measure three parameters – blood glucose, ketone and uric acid – in one single system.

We started the research and development of Exactive Pro in June 2019. As demonstrated in our verification studies, Exactive Pro can achieve high accuracy and precision at wide hematocrit (or HCT, which measures the volume percentage of red blood cells) ranges (blood glucose: 20% to 70%; β-Ketone: 10% to 70%; uric acid: 10% to 70%). The following table sets forth key metrics of Exactive Pro:

	Blood Glucose	**β-Ketone**	**Uric acid**
Measurement range	10~600mg/dL	0.0~8.0mmol/L	150~1200μmol/L
Precision	≤100mg/dL, SD<7.7mg/dL; ≥100mg/dL, CV<7.5%	<1.5mmmol/L, SD<0.075mmol/L; ≥1.5mmmol/L, CV<7.5%	<380μmol/L, SD<42μmol/L; ≥380μmol/L, CV<7.5%
Reaction time	5s	5s	10s
Sample size	Min. 0.5μL	Min. 0.8μL	Min. 1.0μL

Exactive Pro, including our newly developed ketone and uric acid test strips, will be regulated as Class II medical devices in China. The meter, as part of Exactive Pro, is exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials promulgated by the NMPA, as amended. The newly developed ketone and uric acid test strips will be intended for self-testing purposes, and therefore we are required to conduct a registrational clinical trial to validate the effectiveness and safety of these test strips pursuant to relevant NMPA regulations. As of the date of this document, we are performing the registrational clinical trial for ketone and uric acid test strips. We expect to submit the relevant registration applications to NMPA in the second half of 2021. When approved, Exactive Pro is expected to be the first all-in-one product in China with all three parameters automatically code-free. As of the Latest Practicable Date, we were also exploring to equip Exactive Pro with Bluetooth connectivity. Users may receive data on smartphone app and get trends, statistics and other monitoring information. We position Exactive Pro as a multi-parameter device with high measuring accuracy for diabetes self-care and expect to market it through OTC and hospital channels in China and overseas.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET EXACTIVE PRO SUCCESSFULLY.

IVocare Multifunctional POCT

HbA1C, MAU and hs-CRP+CRP are three key indicators in the monitoring and management of diabetes. We are developing a multifunctional POCT analyzer adaptable to three types of IVD assays used for the testing of HbA1C, MAU and hs-CRP+CRP. The POCT analyzer and the three types of IVD assays are exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials promulgated by the NMPA, as amended. To commercialize IVocare multifunctional POCT in China, we are required to register the POCT analyzer and the three types of IVD assays as Class II medical devices with the Zhejiang MPA. In August 2021, we obtained the Class II medical device registration certificate for the POCT analyzer. We submitted Class II medical device registration applications of these three types of IVD assays in December 2020, and expect to receive the Class II medical device registration certificates for them in the second half of 2021.

The following table sets forth key metrics of our multifunctional POCT:

	HbA1C	MAU	hs-CRP+CRP
Reaction time	4.0 minutes	3.5 minutes	3.5 minutes
Sample type	Whole blood	Urine	Whole blood/ serum/plasma
Sample size*	75μL	50μL	75μL
Storage temperature (°C)	4-30	4-30	4-30
Operating temperature (°C)	10-30	10-30	10-30
Shelf life	24 months	24 months	24 months

* including buffer mixture

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR IVOCARE MULTIFUNCTIONAL POCT SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

We focus on developing innovative technologies and medical devices for the monitoring, treatment and management of diabetes. We believe that the success of our operations depends to a large extent on our ability to develop improved diabetes management medical devices. We have a proven track record of independently developing and commercializing diabetes management medical devices and management solutions.

We are engaged in ongoing R&D activities to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, reliability, and to expand the applications of our products, as appropriate. We have a diverse pipeline of product candidates in various stages of development, including our closed loop artificial pancreas, second-generation patch insulin pump system, AiDEX X and our IVD devices, which we anticipate to contribute to our future growth.

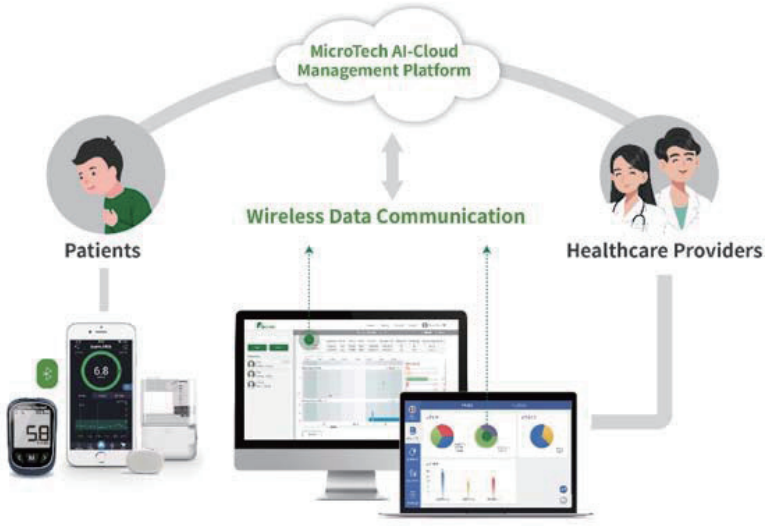
The time required from developing to commercializing a new product varies by product candidate and can be affected by various factors which may be beyond our control, such as clinical trial results and government policies and approvals. We incurred R&D expenses of RMB50.1 million, RMB82.0 million and RMB9.0 million in 2019, 2020 and the four months ended April 30, 2021, respectively.

Besides our diversified product portfolio, we have also developed a series of diabetes management solutions and we strive to build a cloud-based diabetes management platform to provide continuous, proactive and personalized diabetes management solutions worldwide.

Cloud-based Diabetes Management Platform

To fully utilize the data collected or to be collected through our existing and future medical device products, we plan to build a cloud-based diabetes management platform for patients and healthcare providers. The research and development of our cloud-based diabetes management platform is led by professionals with extensive experience in software technology, data analytics and the structuring of medical IT platform. This cloud-based platform will integrate our products, after-sales services, and product and service updates that leverage big data and artificial intelligence technology.

As illustrated below, users of our existing and future products, including patch insulin pump systems, CGMS and artificial pancreas, may record their health data, such as glucose level, when using our products and share these data with us and healthcare providers. After obtaining prior consent of users, our Company and the healthcare providers may also gain access to health data automatically generated in users' daily use of our products. Such data and information are safely encrypted and stored in cloud servers in compliance with applicable laws and regulations. Third parties can access on demand only with appropriate authorization. Users of our products can opt-out from consenting the collection and storage of their health data. Users are also allowed to share with us such data on an anonymous basis and they can delete any such data from time to time. As of the Latest Practicable Date, the data collected in China and overseas were host on cloud infrastructure provided by Ali Cloud and AWS, respectively, and we had entered into service agreements with Ali Cloud and AWS which provided customary terms and conditions.



The cloud-based diabetes management platform is expected to support the post-marketing operation and feedback collection for further R&D of our Equil and other products. Through this cloud-based platform, we also plan to provide value-added services such as data analysis, disease management advising, and telemedicine for patients and healthcare providers.

R&D Team

We have an in-house R&D team of nearly 100 staff, including scholars and scientists from world-renowned universities, as well as elite engineers and seasoned experts. Our R&D team has outstanding interdisciplinary capabilities in the relevant fields, such as mechanical engineering, electrical engineering, software engineering, communication engineering and signal processing, electrochemistry, biomedical engineering and mathematics (algorithm) and artificial intelligence. Over 30% of our R&D staff possess a master or doctorate degree. Our key R&D staff have on average 13 years of relevant experience and more than dozen of our R&D staff has working experience at top medical device companies, such as Medtronic, Johnson and Johnson, Terumo, Flex (or known as Flextronics), among others.

Among our core R&D staff, Dr. Zheng Pan, our Chief Executive Officer, brings us nearly 20 years of industry leadership experience. Dr. Zheng Pan has led a competitive project under a National Major Scientific Research Program in 13th Five-Year Plan Period in 2016. Mr. Dore Chin Mark, our vice president for engineering has over 20 years of industry experience. Mr. Dore Chin Mark has successfully led the launch of a series of medical device products overseas, and he is the inventor of more than 10 issued patents and designs in the U.S. Dr. Yu Fei, our R&D director, is an outstanding scientist in the field of bioelectric chemistry. Dr. Yu Fei has accumulated years of experience in the R&D of diabetes management medical devices. Dr. Yu Fei is the inventor of more than 10 issued patents relating to the biosignal detection. Dr. Yu Fei is also the reviewer of five leading journals, including Biosensor & Bioelectronics, IEEE Sensor and PLOS One. Our core R&D staff have been with our Company since its inception and they are deeply committed to our mission. They have led the R&D of and brought to the global market multiple cutting-edge medical devices in their careers.

Externally, we have built long-standing relationship with industry KOLs, including well-known medical professionals and clinical experts. We leverage their meaningful insights and recommendations to steer our R&D process towards the unmet clinical needs. We have long-term collaborations with experts, universities and research institution in China. For example, we have jointly established the Flexible Electronics Joint R&D Center with Zhejiang University.

To broaden our global research and development networks, we have also established a R&D center in Silicon Valley. As of the date of this document, we had organized a small and targeted group of researchers that perform advanced research in the processing of thin film materials and maintain direct communication with the FDA on regulatory matters. Our R&D center in Silicon Valley is expected to excel at tapping new centers of knowledge and enable us to commercialize products rapidly in the relevant local market.

In recognition of our R&D capability, we were designated as the Key Diabetes Research Center in Zhejiang Province, China. Equil was designated as an Innovative Medical Device Product by the PRC Ministry of Science and Technology. AiDEX G7 has been certified by the NMPA in May 2020 to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA. Our team focused on the R&D of an intelligent cognitive computed based closed loop artificial pancreas, was also awarded as "Leading Innovative Team" by the Science and Technology Department of Zhejiang Province.

Product Design

As of the Latest Practicable Date, we had established and strictly followed an internal protocol pursuant to NMPA regulations, ISO13485 standards and EU regulations on the quality management system of medical devices, including MDD 93/42/EEC and IVD 98/79/EEC and all related amended directives that govern the design and development of our products. The R&D team will join the sales and marketing team to conduct marketing survey and collect information required for and the feasibility of the product development. The R&D team will specify the product function, features, raw materials and manufacturing process in a written report and submit to our project management team and the senior management for approval. We set up our final design plan and product specifications through collaboration across teams. Each team undertakes work in the area of its expertise, which allows us to receive valuable input and guidance in each major aspect of product development. For each project, our project group members will collaborate with production technology team in determining the manufacturing methods, required machinery and manufacturing conditions. Our software development, electronic hardware, and mechanical structure teams are also involved in the optimization of project design. Our quality management team will assist with product testing with respect to its stability, reliability and other quality indicators under the design requirements. Our project management team takes lead in preparing documents and samples for registration inspection.

We often collaborate with major hospitals, labs and universities in China and globally in the R&D of our products. We generally enter into agreements with these hospitals, labs and universities, the terms and conditions of which may vary from project to project and are determined on arm's length discussions.

Clinical Trials

Our clinical affairs team has significant experience in conducting clinical trials for our products. The team is responsible for clinical validation, including the preparation of clinical trial protocols and clinical trial reports. The leaders of our clinical affairs team have on average nearly 20 years of experience in the clinical trial registration and obtaining the overseas registration approval, and nearly 10 years of working experience at major multinational medical device companies.

We conduct clinical trials of our new products in order to obtain the requisite regulatory approvals and collect post-procedure data that can improve and enhance the design and features of our products. In addition, robust clinical data are an important marketing tool for our brand and products. The goal of a clinical trial is to measure the clinical efficacy and safety of a device. Primary parameters for clinical trials are selected based on the intended use of the medical device.

We have a separate regulatory affairs team that is in charge of regulatory communications. The team coordinates the evaluation of registration application, and submit our clinical report together with other materials to the relevant government agencies.

As of the Latest Practicable Date, we had initiated seven clinical trials, including six clinical trials in China. Our clinical data and practices are designed to meet applicable standards and regulatory guidelines.

Collaboration with Clinical Trial Institutions

The NMPA maintains a catalog of hospitals that it has approved as clinical trial centers, from which we select a number of leading hospitals with desirable expertise, patient samples, technology and equipment to conduct our clinical trials. We will meet with the selected participating hospitals to discuss the trial's goals and requirements, as well as to select the leading institution for the trial, which typically will be the largest and best-equipped hospital of the participating hospitals.

We typically enter into an agreement with each selected hospital for each clinical trial, under which we and the participating hospitals prepare a clinical trial protocol following GCP standards that describes in detail the goal of the clinical trial, the risks involved, the overall design, the methods and the procedures of the trial. We submit the relevant documents to the ethics committee of each participating hospital for review. Such documents typically include our clinical trial protocol, draft informed consent to be filled out by patients, draft case report forms to be completed by investigators supervising the clinical trial, and agreement with the hospital to perform the clinical trial. The ethics committees may ask us to revise the clinical trial protocol or other documents before their approval. Once the protocol is approved, any amendment thereafter is required to be reviewed and consented by the ethics committees and the clinical trials are required to be conducted strictly pursuant to the approved protocol.

Pursuant to the agreement, each participating hospital is obligated to conduct clinical trials following the protocol and at the end of the clinical trial, issues a case report based on the collected data. The leading institution gathers case report forms from all participating hospitals, and prepares formal reports of the clinical trial. We make payments according to the agreed schedules and items for the hospitals' services. In line with industry practice, under the agreement, we own all related intellectual property and results from the trial. Each participating hospital is entitled to publish academic papers or attend academic events using the trial results.

Relationships with CROs and SMOs

We use CROs and SMOs to manage, conduct and support our clinical trials. Our CROs provide services such as the implementation and management of clinical research projects as specified in the master agreement or a work order. Our SMOs provide services such as trial site management and subject enrollment support.

We select our CROs and SMOs based on various factors, such as their qualifications, academic credentials and professional experience of their employees and their industry reputations. We generally enter into an agreement regarding each clinical trial or research project with the CRO or SMO. We closely monitor our CROs and SMOs to help ensure their performance will comply with our protocols and applicable laws, regulations and guidelines, which in turn protect the integrity and authenticity of the data from our clinical trials and studies.

We have worked with CROs and SMOs for our clinical trials in China and overseas, including our clinical trials for Equil and AiDEX G7. Under the relevant agreements, we are responsible for the trial preparation, subject enrollment, trial implementation and management, and report preparation, while CROs and SMOs take responsibility for record keeping to ensure the compliance of clinical trial process with applicable laws, regulations and guidelines. We provide the CROs and SMOs with their required materials and information and make payments in accordance with the payment schedule agreed by parties. CROs and SMOs may further assist us in the trial preparation and management pursuant to our particular request, for which extra fees will be incurred. Under the agreements, we own all intellectual property and trial results. CROs and SMOs are obligated to keep all non-public information and data from the trials confidential, and return related materials to us at the end of our contract term.

Other Collaboration

Collaboration with the Institute of Microelectronics and Nanoelectronics of Zhejiang University ("ZJU ISEE")

In October 2016, we entered into a four-year collaboration agreement with ZJU ISEE (the "**ZJU ISEE Agreement**"), where we agreed to jointly establish a Flexible Electronics Joint R&D Center (the "**Joint R&D Center**") to improve the manufacturing process of using flexible polyimide as a primary material for glucose sensors. Under the ZJU ISEE Agreement, ZJU ISEE agrees to provide access to its research sites, laboratories and equipment, and we will provide research funds to sponsor the Joint R&D Center's R&D activities on a case-by-case basis.

Unless otherwise agreed by parties, with respect to projects fully sponsored by us, we will own the research achievements, including intellectual property rights and related economic interests, and ZJU ISEE will retain the right to use such research achievements solely for the purposes of research and development. With respect to projects mutually funded, both parties will share the research achievements in proportion to the funding amount of each.

The agreement can be terminated upon both parties' mutual agreement, and parties can enter into separate agreements based on actual needs.

The ZJU ISEE Agreement had expired in October 2020 and parties did not enter into any new agreement as of the Latest Practicable Date. We had provided research funds of RMB150,000 during the term of the ZJU ISEE Agreement. We did not acquire any intellectual property rights pursuant to this agreement.

DATA PRIVACY AND PROTECTION

We currently operate substantially all our businesses in China. When conducting clinical trials for our products and providing services to our customers, we may have access to certain data of medical institutions and individual patients. Certain types of such data may fall into the scope of personal information under applicable laws and regulations. We have designed strict data protection policies and stringent IT security protocols to ensure that the collection, use, storage, transmission and dissemination of such data are in compliance with applicable laws and with prevalent industry practice. These internal policies and protocols lay emphasis on the encryption and protection of information for all cloud-based servers, local servers, databases, operating system users and business users. We have established a special department that is responsible for the implementation of these policies and protocols, including the management of passwords. In addition, we strictly manage the entry and exit of our controlled computer room and require immediate reporting and management of any data and security breach events. Externally, users of our products can opt-out from consenting the collection and storage of their health data. Users are also allowed to share with us such data on an anonymous basis and they can delete any such data from time to time. These data and information are safely encrypted and stored in cloud servers in compliance with applicable laws and regulations. Third parties can access on demand only with appropriate authorization.

As confirmed by our PRC Legal Advisor, we were not subject to any material claims, lawsuits, penalties or administrative actions which had a material and adverse effect on our business, financial condition or results of operations relating to non-compliance with applicable PRC laws and regulations with respect to data privacy and protection.

MANUFACTURING

Our principal manufacturing facility is located at our headquarters in Hangzhou, China. As of the Latest Practicable Date, we owned manufacturing facilities with an aggregate area of approximately 15,000 sq.m., including a 1,500 sq.m. ISO Class 7 clean-room space and an 80 sq.m. ISO Class 8 clean-room space, for the production and pre-delivery inspection of our products. As of the Latest Practicable Date, our facility in Hangzhou was primarily used for the production of Equil and BGMS products.

The following table sets forth the production capacity, actual production volume and utilization rate of our manufacturing facility in Hangzhou for the periods indicated:

	For the year ended December 31,		For the four months ended April 30,
Products	**2019**	**2020**	**2021**
	(in thousand, except for percentages)		
Equil – Patch pump and PDA			
Production capacity (units)[1]	5.6	7.0	2.0
Actual production volume (units)	4.1	5.6	1.6
Utilization rate (%)[2]	72.9	79.5	79.0
Equil – Disposables			
Production capacity (units)[1]	385.3	795.3	271.9
Actual production volume (units)	305.3	778.9	232.6
Utilization rate (%)[2]	79.2	97.9	85.5
Blood glucose meters			
Production capacity (units)[1]	461.5	720.4	276.4
Actual production volume (units)	334.3	659.5	229.9
Utilization rate (%)[2]	72.4	91.5	83.2
Test strips			
Production capacity (units)[1]	64,441.6	101,911.7	36,964.6
Actual production volume (units)	51,738.5	85,480.6	34,222.4
Utilization rate (%)[2]	80.3	83.9	92.6

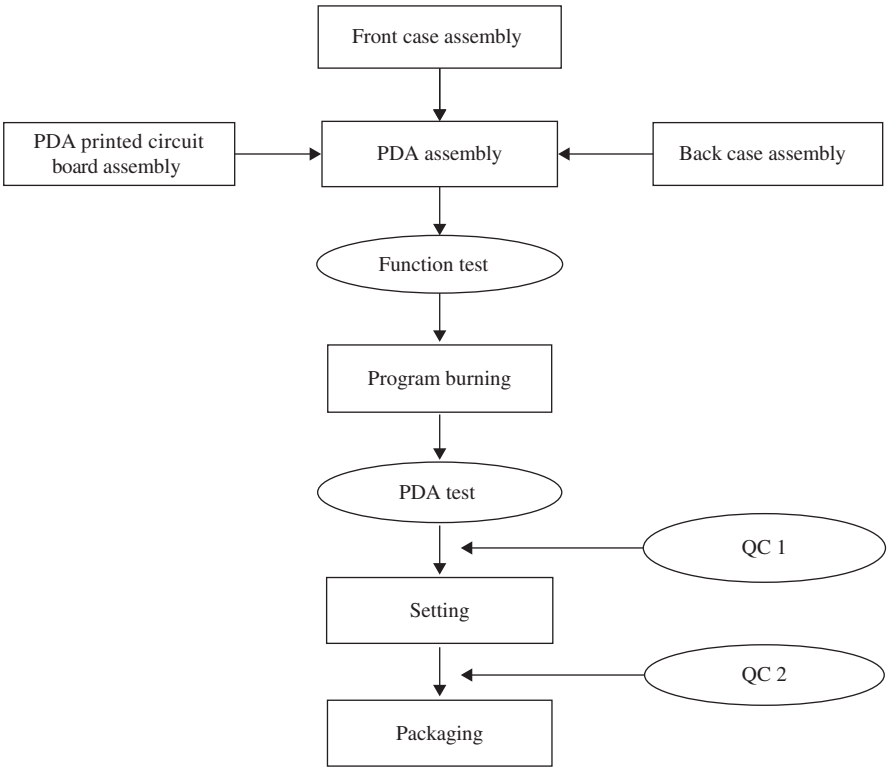
Notes:

(1) Production capacity is computed based on 235 effective production hours per month.

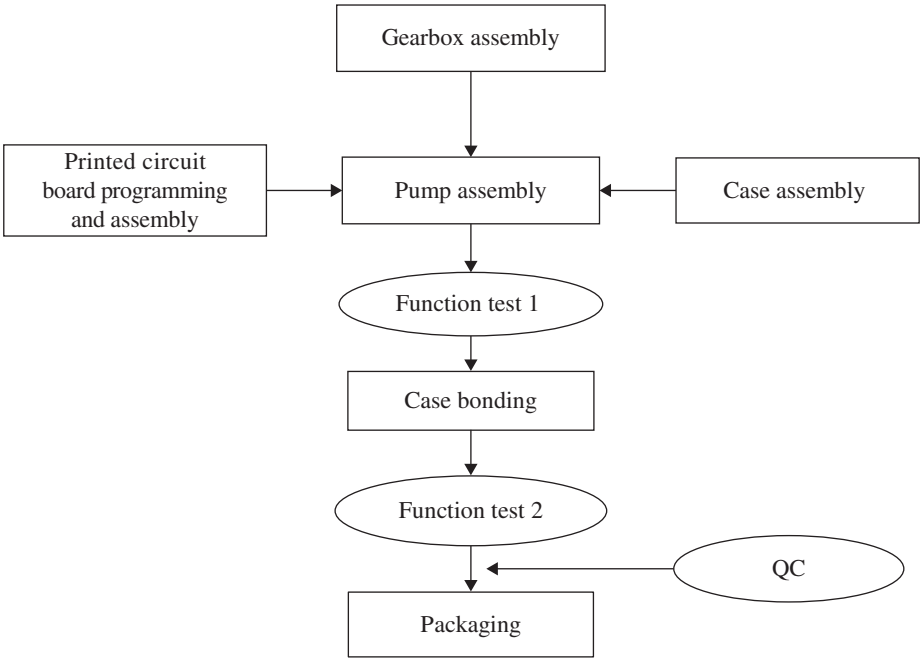
(2) Utilization rate equals actual production volume divided by production capacity.

Our patch insulin pump system is mainly composed of the PDA, the pump and disposables (the insulin reservoir and cannula). The manufacturing of these components primarily involves the following steps:

(A) Portable diabetes assistant

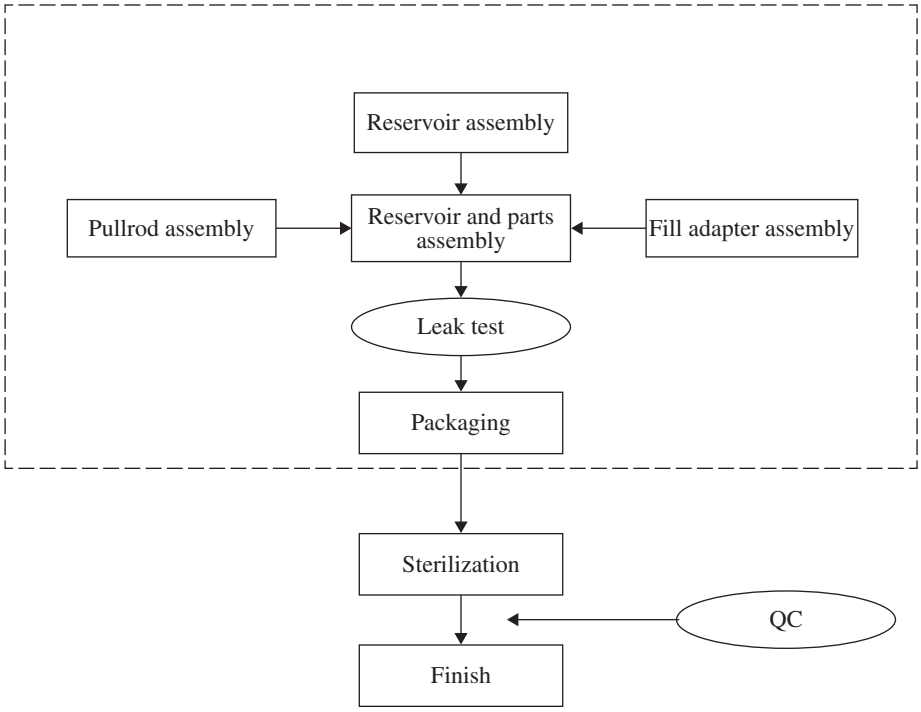


(B) Patch pump

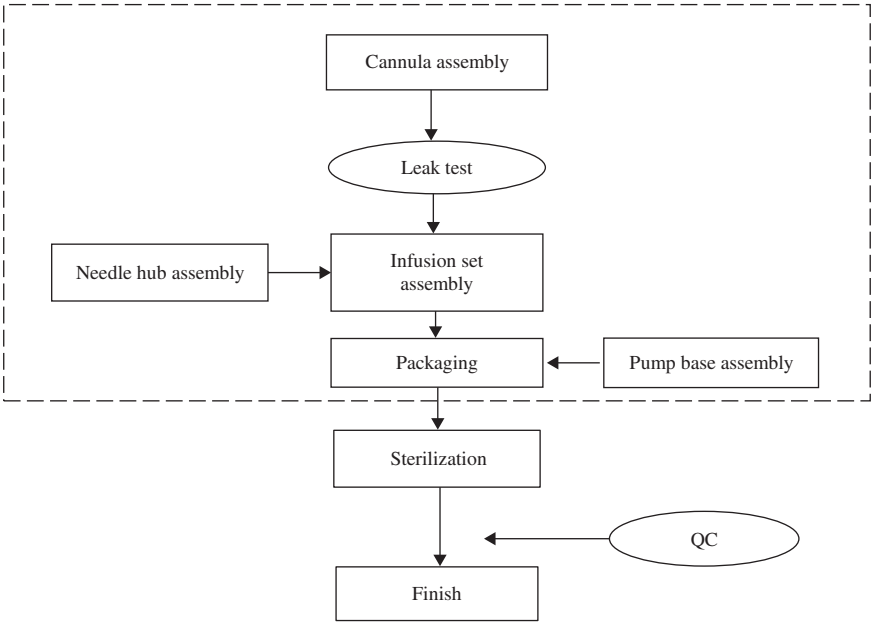


(C) Disposables

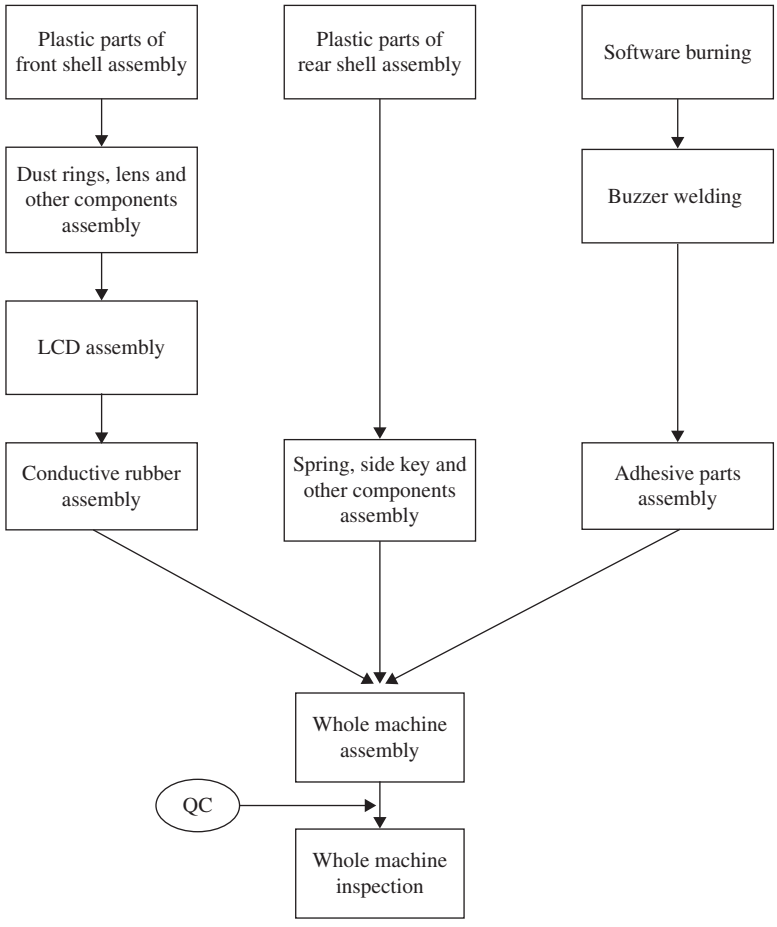
Insulin reservoir



Cannula



The manufacturing of our blood glucose meters primarily involves the following steps:



The steps within the dotted line above are conducted in a controlled clean environment (ISO Class 7 or 8), and the other steps are conducted in regular environment. We have implemented quality management systems as part of our manufacturing processes. See "—Quality Control."

We conduct all the key manufacturing process of our products in-house. The head of our manufacturing team in China has extensive manufacturing experience in the medical devices industry. Our integrated production process increases our production efficiency, reduces our dependence on third parties, and enables us to adjust our production in a timely fashion to respond to changes in market demand for our products.

We have entered into agreements with an Independent Third Party to delegate the patch of printed circuit boards, tape die-cutting and sterilization of finished products. We are able to monitor and control the standard and quality of these delegated work through our agreements with third parties. The delegated party is obligated to conduct these manufacturing procedures as required by the standard stipulated in the quality assurance agreements. We retain the right to inspect the delegated party's facility and equipment, evaluate whether it adheres to the required standards and request the delegated party to improve accordingly. Also, the delegated party's work is subject to our examination, and we retain the right to return the product for further sterilization. To help ensure a consistent standard of these procedures, we tend to delegate each type of work to one primary entity.

We primarily use various types of customized automatic production lines, assembly equipment, dispensers, laser cut machines and print machines to manufacture our products. We purchase machinery from multiple suppliers, and we are able to purchase such machinery from alternative suppliers. We have implemented a comprehensive inspection and maintenance system for our machinery. We have also put in place measures and plans for emergency maintenance. During the Track Record Period, we had not experienced any significant or prolonged interruptions of our machinery due to equipment or machinery failure.

We believe that our location gives us an advantage in manufacturing over our international competitors. We have access to China's vast labor pool and enjoys various governmental supports to attract high-caliber talents, which makes it easier for us to hire people with the appropriate skills for our production. We typically require new employees to undergo a strict training and pass our evaluation 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 yields high-quality production and enables us to enhance our manufacturing efficiency.

SALES AND MARKETING

We use a combination of our in-house sales and marketing team and a network of independent distributors to sell our products in China and globally. As of the Latest Practicable Date, we had a sales and marketing team of 135 members, and our core sales personnel had on average more than 15 years of experience working in the relevant field with us.

Our in-house sales and marketing team tracks and analyzes applicable local laws and regulations and government policies as well as market data of our products in order to formulate regional and overall marketing strategies effectively.

Our Marketing Model

Our marketing strategy focuses on building awareness for the benefits of our products and generating demand and acceptance of our products among healthcare professionals and patients through our user-centric and clinical-data-driven promotion.

Our highly trained sales and marketing team focuses on interacting with physicians and patients to educate them about, and train them in the use of, our products. Such interaction is fostered through regular visits and communications, on-site demonstration of our products, training and education programs. For example, we are able to educate and train physicians in respect of CSII therapy, and present the innovative features of Equil that make it well-positioned to satisfy the clinical need in CSII therapy. Although patients are the end users of our products, physicians, procurement departments of hospitals and other medical institutions decide what products to stock and physicians typically recommend to patients what products to use. Based on our experience, as physicians become more knowledgeable and experienced with our products, they will be more likely to recommend our products. In addition to accelerating market awareness and adoption of our products, our communications with these physicians also provide us with continual feedback on our products and trends in the market which helps guide our R&D projects.

We also regularly organize and attend educational symposia, conferences, seminars, and other activities at national, regional and local levels. For example, we have sponsored and attended conferences that gathered leading international experts focused on therapeutic areas of diabetes and other chronic diseases, including the 17th International Congress of Immunology of Diabetes Society, China Diabetes Society Annual Meetings, and Endocrinology Society of China Annual Meetings. Because of our advanced technology and our first-mover experience, our products have been among the central topics of academic discussions and examples for training, and our R&D experts and management have been invited as speakers to introduce their practices in this field. These seminars and conferences allow us to introduce our products, share our clinical results and enhance experts' awareness of clinical benefits of our products.

In addition, we leverage our network with KOLs and depend on KOLs to introduce and recommend our products to physicians and hospitals. KOLs have academic incentives in learning the latest disease treatment options available within their therapeutic areas, as well as introducing cutting-edge technologies and products that they believe have clinical benefits to other medical professionals. We provide these experts with detailed information of our products and help them make independent comparisons among competing products in the market. We believe that these KOLs' independent views on our products help increase the market recognition of our products among the wider medical community across the country. We typically solicited and built our network of KOLs through clinical trial collaborations and communications with them through academic conferences and seminars. When selecting KOLs for a specific academic event, we consider factors such as the participating doctor's vocational affiliation, the purpose and scale (local, regional or national) of the event, as well as the KOL candidate's academic and professional backgrounds, medical specialties and reputation in the industry. We also consider whether they have participated in clinical studies or published academic articles related to related products. We usually choose physicians who have used our products before as KOLs.

In 2019, 2020 and the four months ended April 30, 2021, we engaged three, six and four KOLs, respectively. During the Track Record Period and up to the Latest Practicable Date, all of the KOLs we engaged, to the best of our Directors' knowledge, were Independent Third Parties and none of them had any past or present relationship (business or otherwise) with our Group, our Shareholders, Directors, Supervisors, senior management or any of their respective associates. The KOLs we engaged during the Track Record Period have years of experience in the treatment and research of diabetes, some of whom are also council members or sit on the committee of Chinese Medical Doctor Association and China Diabetes Society. We typically enter into agreement with the KOLs for their services in giving presentations in academic conferences and on-site training, coaching and proctoring physicians in hospitals. The service agreements typically set forth the type of services, payment of compensation, conditions of terminations and customary confidentiality requirements. Under the service agreement, KOLs are required to undertake that (i) they have obtained the approval of their employer hospitals or other organizations; (ii) they will abide by applicable laws and regulations in rendering their services; and (iii) their rendering of services under relevant service agreements are intended to promote medical knowledge exchanges, medical development, medical continuing education, and public disease education in the medical field and should not exert any undue effect on their prescription behavior or other medical professional practices.

We compensate KOLs in the performance of their services on an arm's length basis and in accordance with the industry standards. We typically compensate our KOLs based on the time and nature of services they provide, and have set standards and limits on the compensation of KOLs, depending on the level and location of conferences, with details set forth in respective service agreement. In each of 2019, 2020 and the four months ended April 30, 2021, such compensation expenses represented less than 1% of our total selling and distribution expenses for respective periods.

Besides our primary academic marketing model, we also rely on our distributors to promote and market our products. Each of our distributors has its own sales force that focuses on marketing in its particular territory and assigned hospitals. Distributors have engaged in promoting our products through their network of hospitals and physicians. For details, see "—Our Sales Arrangements—Sales through distributors."

Our Sales Arrangements

In line with the industry practice in the medical devices industry, we sell substantially all of our products to distributors, who are our customers, and they resell our products to hospitals, pharmacies or individual customers. Our in-house sales and marketing team primarily focus on enhancing professionals' knowledge and understanding of the usage, clinical effects and advantages of our products. We believe this distribution model helps extend our coverage in a cost-effective manner while retaining proper control over our distribution network and marketing and promotion process.

We set annual and monthly/quarterly sales targets of our products at the beginning of each year and each quarter. We assess information our marketing personnel gathers from hospitals and other customers and adjust our sales forecasts accordingly on a monthly basis. We also refer to the historical numbers of purchases for our sales projections. We believe that the information provided by our sales and marketing team allows us to estimate market demand for our products.

Since the fourth quarter of 2019, we launched a pilot program for the marketing and promotion of Equil. In the pilot program, we sell Equil to our distributors, who, may allow patients that are recommended or required to receive short-term intensive insulin therapy with insulin pump to rent Equil for a specified period a time. Under this model, distributors are the ultimate owners of the purchased product.

The following table sets forth a breakdown of our revenue generated from distributors and direct sales for the periods indicated:

	For the year ended December 31,				For the four months ended April 30,			
	2019		2020		2020		2021	
	RMB'000	*%*	*RMB'000*	*%*	*RMB'000*	*%*	*RMB'000*	*%*
					(Unaudited)			
Sales to distributors[(1)(2)]	51,251	98.8	73,277	97.3	17,606	99.2	36,687	94.4
Direct sales[(3)]	612	1.2	2,000	2.7	145	0.8	2,164	5.6
Total	51,863	100.0	75,277	100.0	17,751	100.0	38,851	100.0

Notes:

(1) Including RMB116 thousand, RMB169 thousand, RMB29 thousand, and RMB15 thousand sales to sub-distributors in 2019, 2020 and the four months ended April 30, 2020 and 2021, respectively.

(2) The following table sets forth a breakdown of our sales to distributors by geography:

	For the year ended December 31,		For the four months ended April 30,	
	2019	2020	2020	2021
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
China	42,619	58,111	14,941	22,101
Overseas	8,632	15,166	2,665	14,586
	51,251	73,277	17,606	36,687

(3) During the Track Record Period, we did not have any direct sales overseas.

In 2019, 2020 and the four months ended April 30, 2020 and 2021, sales of our Equil patch insulin pumps to Class III hospitals were made through our distributors, and such sales accounted for 2.7%, 4.4%, 2.8% and 1.6% of our total sales of Equil patch insulin pumps in China.

Sales through distributors

- *Selection of distributors*

Our sales and marketing team screens and selects distributors whom we believe have the required qualifications and capabilities and are suited to our strategic marketing model, and establishes and maintains resource sharing with our distributors to effectively execute our marketing strategies specifically tailored to each geographic location and the hospitals located within their locations.

Upon selecting distributors, we will first evaluate their qualifications. Our distributors primarily engage in the medical device distribution business. We select our distributors based on their experience in the medical devices industry, particularly in diabetes devices. In addition, they must possess the requisite business licenses and permits to sell medical devices in the respective jurisdiction and have established relationships with hospitals and physicians within their designated territory. Before we appoint a distributor, we assess its sales staff and management to help ensure that they have the appropriate educational background and professional skills. We also consult with the hospitals regarding our choice of distributors and consider any recommendation from the hospitals. We review the qualifications of our distributors when our contracts with them are due to be renewed. Our relationship with our distributors is seller/buyer relationship not principal/agent relationship. During the Track Record Period, none of our distributors had any past or present relationship (business or otherwise) with our Group, our Shareholders, Directors, Supervisors, senior management or any of their respective associates.

- *Rights and obligations relating to the sales of our products*

We do not allow overlap of distributors among hospitals. Distribution relationships between our distributors and the respective hospitals are exclusive. We also require distributors to file with us if they engage any sub-distributor in their designated geographic regions and enter into distributorship agreement with such sub-distributors to abide by our policies. In the event that our distributors engage sub-distributors to sell our products, such sub-distributors will also be required to enter into distributorship agreement with us and abide by our policies and regulations. The material terms of the distributorship agreements that the distributors enter into with sub-distributors are substantially same with those in the distributorship agreements we enter into with our distributors, the principal terms of which are summarized in the paragraphs below. The amount of the products we sell to a distributor depends on the number of sales generated from hospital, pharmacies and individual customers in the designated area. We recognize revenue from distributor sales when control of goods or services is transferred to the customers.

We generally store our products in warehouses and deliver our products directly to distributors. Our distributors are responsible for collecting payments from their customers, and are required to pay us for the products regardless of whether they receive payments from their customers.

We enter into agreements with our distributors that specify terms including their designated distribution area and hospitals, target order amount and credit terms. The principal terms are summarized below.

Duration	The distribution agreements typically have a term of one year.
Designated geographical regions	The geographical regions for which a distributor is responsible are designated. A distributor is prohibited from selling our products outside its designated geographical regions without our prior consent. We may request a distributor to make a deposit to guarantee its distributions within the designated geographical regions.
Target order amount	An annual target order amount is set and further scheduled by month or by quarter. We are entitled to terminate the distribution if the distributor fails to achieve 50% of the target order amount during the term of the distribution agreement.
Transportation	The distributor may elect to (i) pick the products, arrange for and bear the costs and risk of loss of the transportation; or (ii) request us to transport products and bear the costs and risk of loss of the transportation, while we will not bear the costs of transportation if the distributor fails to meet a stipulated purchase amount.
Product returns	In general, the distributor may not return products to us or exchange products other than for product quality issues and any such request shall be made with a stipulated period of time upon receipt of our products. We will bear the costs of transportation for returning the defective product if quality issues are confirmed after inspection.

Warranty	We provide a four-year warranty on our patch insulin pump and a ten-year warranty on our blood glucose meters.
Termination	The agreement may be terminated by us when, among other things, the distributor breaches pricing provision or fails to meet 50% of the target order amount. The distributor can terminate when we fail to correct our breach of contract within a stipulated period of time after receiving their notice of correction.
Regulatory compliance	The distributor is required to comply with all applicable laws and regulations, including, among other things, anti-bribery and anti-kickback laws and regulations. The distributor is also required to obtain relevant permits to sell and distribute medical devices and maintain storage facilities compliant with regulatory standards on medical device storage, and provide us with copies of the relevant licenses, permits and certificates.

We conduct annual review of our distributors, based on their financial performance, business performance and regulatory compliance. Distributors' financial performance is primarily evaluated by their credit records with us during each period, and the evaluation of their business performance is primarily based on the distributors' sales performance, specifically whether they meet the target order amount, and the designated hospitals' feedbacks. We also review their compliance with applicable laws and regulations. We retain the discretion to adjust their credit terms, renegotiate order price and certain other commercial terms with them based on the review results. Our sales and marketing department monitors, manages and supports the activities of our distributors to help ensure that they comply with our guidelines, policies and procedures. We require distributors to provide written commitments to us which stipulate our requirements for various aspects of distributors' operations, such as prohibiting distributors from providing any form of improper benefits. With respect to our sub-distributors, we require our distributors to enter into distributorship agreements with any sub-distributors they engage to have such sub-distributors abide by our policies. Our distributors are also contractually obligated to assist us in the management of sub-distributors in designated geographic regions, including monitoring the performance and compliance status of these sub-distributors. To the best of our knowledge, none of our distributors or sub-distributors, or the Group's employees was or has been the subject of (or otherwise involved in) complaints, investigations, or regulatory enquiries in relation to, any non-compliance incidents, bribery or kickback arrangements during the Track Record Period and up to the Latest Practicable Date.

According to our trading terms with customers, prepayment is normally required, except for certain customers, where credit period is allowed, and the credit period is generally within three months. During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial condition.

- *Relationship with distributors*

As of December 31, 2019 and 2020 and April 30, 2021, we had a total of 287, 374 and 382 distributors for the sales of our products, respectively. As of December 31, 2019 and 2020 and April 30, 2021, our distributors engaged a total of one, one and three sub-distributors, respectively. According to the Notice on Opinions on the Implementation of the "Two-invoice System" in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)的通知》) (the "**Notice**"), jointly issued by the Medical Reform Office of the State Council (國務院醫改辦) and other seven ministries and commissions on December 26, 2016, the "Two-invoice System" refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. As of the Latest Practicable Date, most provinces in China implemented the Two-invoice System in the field of medicines and high-value medical consumables, including Jiangsu, Shanghai and Hubei provinces, where our distributors engaged sub-distributors, for the sales of insulin pumps.

Pursuant to the Notice of the General Office of the State Council on Promulgation of the Reform Plan for the Control of High-value Medical Consumables, promulgated by the State Council and came into effect on July 19, 2019, high-value medical consumables refer to the medical consumables that are directly used for human bodies in great demand clinically and priced relatively high, which have strict requirements for safety and can pose heavy burdens on patients. The Notice on Promulgation of the Good Practices for Centralized Procurement of High-Value Medical Consumables (for Trial Implementation), promulgated by the Ministry of Health, the Office for Rectifying Malpractices of the State Council, the National Development and Reform Commission, the Ministry of Supervision, the State Administration for Industry and Commerce, the Food and Drug Administration on December 17, 2012, attached a reference catalogue of high-value medical consumables, which did not include the Company's products. As of the Latest Practicable Date, we had not received any notification from the competent authorities which state that our products should be classified as high-value medical consumables. As advised by our PRC Legal Advisor, based on the aforementioned and public searches of products classified as high-value medical consumables, as of the Latest Practicable Date, none of our commercialized products, including insulin pumps, fell into the scope of high-value consumables. As such, the products we sold through sub-distributors in these geographic regions are not within the scope regulated by the Two-invoice System. As advised by our PRC Legal Advisor, the engagement of sub-distributors in our distributorship model during the Track Record Period and as of the Latest Practicable Date complied with the

Two-Invoice System. However, as of the Latest Practicable Date, there had been a few provinces in China, such as Shaanxi Province, implementing "Two-invoice System" in the field of all medical consumables, including low-value medical consumables. If more provinces, including the provinces where our distributors engaged sub-distributors during the Track Record Period, apply the Two-invoice System to our products, we will prohibit our distributors from engaging such sub-distributors in these provinces with respect to sales to public hospitals, seek replacement distributors to cover and expand sales to local public hospitals in the relevant geographic region, or sell our products to public hospitals directly, to comply with the Two-invoice system. See "Risk Factors—Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain" for details of risk factors associated with the trend of wide implementation of the Two-invoice System.

The following table sets forth the changes in the number of our distributors for the periods indicated:

	For the year ended December 31,		For the four months ended April 30,
	2019	**2020**	**2021**
As of the beginning of the period	227	287	374
Additions of new distributors	147	152	55
Termination of existing distributors	87*	65	47
Net increase in distributors	60	87	8
As of the end of period	287	374	382

Note:

* We terminated our agreements with a significant number of distributors in 2019, as we enhanced the qualification and capability requirements for our distributors during the screening and selection process to further optimize our distribution network. In 2019, 2020 and the four months ended April 30, 2021, the revenue contributed by distributors which we terminated agreements in the Track Record Period was RMB11.0 million, RMB4.2 million and nil, respectively.

Direct sales

In addition to the sales through our distributors, we sell a small portion of our products directly to large pharmacies and individual customers. During the Track Record Period, we did not have any disputes with the large pharmacies and individual customers relating to the settlement of trade receivables.

Pricing

During the Track Record Period, we primarily sell our products to our distributors. Our domestic distributors negotiate and set retail prices directly with hospitals, and such retail prices shall not be less than the suggested resale prices set in the distributorship agreement without our prior consent. We also conduct regular checks on their compliance to our pricing requirements. The retail price of our products sold by our overseas distributors may vary from country to country, subject to factors such as prices of competing products and local insurance coverage. For our direct sales to customers, we negotiate the price directly with relevant customer.

As of the Latest Practicable Date, Equil, our Core Product, had not been included under the national public medical insurance program in China. In light of current circumstances, we believe that the likelihood that our Core Product will be included in the national public medical insurance program in China in the near future remains relatively low. However, we observed that certain provincial or municipal government may cover Type 1 diabetes patients under 18 years old in relevant provincial or municipal insurance programs. The national public insurance coverage or reimbursement level in China for insulin pumps is subject to the insurance programs initiated by local governments and insurance companies with different co-pay levels. If our Core Product is included in public medical insurance programs, we may face downward pricing pressure, nevertheless, it will also increase the patient affordability and therefore further promote the market growth of our Core Product. See "Risk Factors—Downward change in pricing of our products may have a material adverse effect on our business and results of operations." In the event that such price cut and reimbursement fail to lead to an increase in our sales, our results of operations may be adversely affected. See "Risk Factors—Our sales may be affected by the level of medical insurance reimbursement patients receive for using our products."

CUSTOMERS

During the Track Record Period, we derived substantially all of our revenue from the sales of Equil and BGMS products.

For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, all of our five largest customers were distributors and the aggregate sales to our five largest customers were RMB6.8 million, RMB11.2 million and RMB13.1 million, representing 13.2%, 14.9% and 33.7% of our revenue, respectively. Sales to our largest customer for the same periods were RMB1.6 million, RMB3.1 million and RMB8.7 million, representing 3.1%, 4.1% and 22.4% of our revenue, respectively. The following is a summary of the sales to our five largest customers for the periods indicated:

Five Largest Customers for the Year Ended December 31, 2019	Length of Relationship as of the Latest Practicable Date	Company Background	Credit Terms	Sales Amount	Percentage of Revenue
				RMB'000	
Customer A	June 2018 – present	A private company that engages in the sales of Class II and III medical devices	Delivery against payment	1,621	3.1%
Customer B	June 2018 – present	A private company that engages in the sales of Class II and III medical devices	Delivery against payment	1,380	2.7%
Customer C	June 2014 – present	A private company that engages in the sales of Class II and III medical devices	Delivery against payment	1,311	2.5%
Customer D	July 2018 – present	A private company that engages in the sales of Class I, II and III medical devices	60 days	1,283	2.5%
Customer E	September 2018 – present	A foreign company that engages in the sales of medical devices	30 days / delivery against payment	1,224	2.4%
Total				6,819	13.2%

Five Largest Customers for the Year Ended December 31, 2020	Length of Relationship as of the Latest Practicable Date	Company Background	Credit Terms	Sales Amount	Percentage of Revenue
				RMB'000	
Customer D	July 2018 – present	A private company that engages in the sales of Class I, II and III medical devices	60 days	3,106	4.1%
Customer F	April 2019 – present	A private company that engages in the sales of Class I and II medical devices	Delivery against payment	2,638	3.5%
Customer G	May 2020 – present	A foreign company that engages in the sales of medical devices	30 days	2,123	2.8%
Customer H	March 2020 – present	A foreign company that engages in the sales of medical devices	30 days to 60 days	1,690	2.3%
Customer I	January 2017 – present	A private company that engages in the sales of Class II and III medical devices	60 days	1,659	2.2%
Total				11,216	14.9%

Five Largest Customers for the Four Months Ended April 30, 2021	Length of Relationship as of the Latest Practicable Date	Company Background	Credit Terms	Sales Amount	Percentage of Revenue
				RMB'000	
Customer G	May 2020 – present	A foreign company that engages in the sales of medical devices	30 days	8,705	22.4%
Customer J	January 2021 – present	A private company that engages in the sales of medical devices	Delivery against payment	1,905	4.9%
Customer F	April 2019 – present	A private company that engages in the sales of Class I and II medical devices	Delivery against payment	880	2.3%
Customer I	January 2017 – present	A private company that engages in the sales of Class II and III medical devices	60 days	823	2.1%
Customer K	March 2019 – present	A private company that engages in the sales of Class I, II and III medical devices	Delivery against payment	778	2.0%
Total				13,091	33.7%

All of our five largest customers during the Track Record Period are Independent Third Parties. During the Track Record Period, none of our Directors or any Shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following the completion of the [**REDACTED**] (but without taking into account the exercise of the [**REDACTED**]) nor any of their respective associates had any interest in any of our five largest customers.

CUSTOMER SERVICE

Given the chronic nature of diabetes, we believe that thorough training and ongoing customer support are important to develop a long-term relationship with hospitals and end users. We provide the following reliable, effective and satisfactory customer services, which contributes to the improvement of user experience and product satisfaction.

- *Comprehensive training support.* We are dedicated to providing comprehensive support to assist physicians and other healthcare professionals in training patients receiving CSII therapy regarding the use of our products. Besides regular on-site visits, we collaborate with China Nursing Association to provide clinical processes and guidelines to certify nurses through Certified Trainer Program. In addition, we have established a network of certified pump trainers ("**CPTs**"), consisting of our in-house and our distributors' customer service staff. We provide our CPTs with a training kit, including relevant methodology and documentations, as a guide for them to train patients on the effective use of our products.

- *24/7 customer support*. We provide 24/7 customer support to provide training to healthcare professionals and users of our products and handle all kinds of customer queries and complaints regarding our products and services. They are able to seek technical supports, make queries and file complaints on the quality of our products and adverse events after use via various channels, such as phone calls, online written instant messaging, and face-to-face communications. We had not received any major customer complaints during the Track Record Period and up to the Latest Practicable Date.

- *Severe adverse event reporting and product recalls*. We have an operations team dedicated to tracking and recording severe adverse events. If the team determines that an incident involving our product constitutes a major adverse event under NMPA regulations, we will report the incident to the NMPA and assess the cause for the adverse events. Our operations team also investigates and analyzes the cause of issue raised by our customers and refers the quality issue to our management and relevant responsible departments for resolution and correction. We will recall our products for quality issues when necessary. During the Track Record Period and up to the Latest Practicable Date, there had not been any product recalls due to quality issues.

RAW MATERIALS AND SUPPLIERS

Suppliers

For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, purchases from our five largest suppliers in aggregate accounted for 33.7%, 19.3% and 21.5% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 19.4%, 5.8% and 6.6% of our total purchases for the same periods (including value added tax), respectively. During the Track Record Period, our purchases mainly include raw materials, softwares, equipment and services from third parties. The following is a summary of the purchases from our five largest suppliers for the periods indicated:

Five Largest Suppliers for the Year Ended December 31, 2019	Length of Relationship as of the Latest Practicable Date	Purchases	Credit Terms	Purchase Amount	Percentage of Total Purchase
				RMB'000	
Supplier A	May 2018 – April 2019	Infrastructure engineering service	Payment by schedule	15,901	19.4%
Supplier B	October 2019 – April 2020	GMP installment	Payment by schedule	5,840	7.1%
Supplier C	July 2016 – present	Plastic materials	Monthly payment	2,129	2.6%
Supplier D	April 2019 – present	Technology R&D and Software	Payment by schedule	1,947	2.4%
Supplier E	October 2018 – present	Electronic materials	Delivery against payment	1,831	2.2%
Total				27,648	33.7%

Five Largest Suppliers for the Year Ended December 31, 2020	Length of Relationship as of the Latest Practicable Date	Purchases	Credit Terms	Purchase Amount	Percentage of Total Purchase
				RMB'000	
Supplier A	May 2018 – April 2019	Infrastructure engineering service	Payment by schedule	5,780	5.8%
Supplier F	March 2020 – June 2020	Decoration service	Payment by schedule	4,303	4.3%
Supplier C	July 2016 – present	Plastic materials	Monthly payment	3,454	3.5%
Supplier E	October 2018 – present	Electronic materials	Delivery against payment	3,134	3.2%
Supplier G	March 2019 – present	Circuit boards	Delivery against payment	2,470	2.5%
Total				19,141	19.3%

Five Largest Suppliers for the Four Months Ended April 30, 2021	Length of Relationship as of the Latest Practicable Date	Purchases	Credit Terms	Purchase Amount	Percentage of Total Purchase
				RMB'000	
Supplier C	July 2016 – present	Plastic materials	Monthly payment	1,632	6.6%
Supplier G	March 2019 – present	Circuit boards	Delivery against payment	1,345	5.4%
Supplier H	September 2015 – present	Circuit boards	Monthly payment	794	3.2%
Supplier I	November 2018 – present	IC components	Monthly payment	789	3.2%
Supplier J	June 2020 – present	Equipment	Delivery against payment	770	3.1%
Total				5,330	21.5%

All of our five largest suppliers during the Track Record Period are Independent Third Parties. During the Track Record Period, none of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [**REDACTED**] (but without taking into account the exercise of the [**REDACTED**]) nor any of their respective associates had any interest in any of our five largest suppliers.

Raw Materials

For the production of our diabetes products and product candidates, our principal raw materials are printed circuit boards, wafer parts, motors and LCD panels, and other raw materials include packaging materials and plastic parts. The raw materials we sourced from our suppliers are generally readily available in the market through many suppliers. We believe we have alternative sources for our principal raw materials with comparable quality and prices. We have not experienced any significant difficulties in maintaining reliable sources of supplies and expect to be able to maintain adequate source of quality supplies in the future. As of the Latest Practicable Date, our principal raw material suppliers were based in China, from whom we purchased raw materials on an as-needed basis.

We generally enter into supply agreements and maintain long-term relationships with our principal raw material suppliers. Our agreement with suppliers typically lists our quality requirements. For some principal raw materials, we also enter into a separate quality assurance agreement with the relevant suppliers. We will decided whether to accept the supply upon inspecting and examining the materials. We make prepayments to some of our suppliers for raw materials, and our other suppliers for raw materials usually provide us with a credit term of up to 30 days.

INVENTORY

Our inventories consist of raw materials, work in progress and finished goods. We have established inventory policies, management procedures and provide adequate training sessions on inventory management. Our procurement department manages our inventory levels by monitoring in real time our production activities and sales orders and also taking into consideration any emerging trends through discussions with our sales and marketing department. Based on effective sales orders and forecast information, the planning department develops a production and inventory plan, which is updated on a monthly basis, and places orders with suppliers for any inventory which is expected to decline below targeted levels.

We generally maintain an inventory level of one- to two-month sales volume for our finished goods and four-to-eight-week supply of our raw materials, and such level will vary according to the demand of our customers, sales and production plans. We store substantially all our inventories in our headquarters in Hangzhou, Zhejiang Province, China.

Our raw materials are typically not subject to expiration. We have set up the safety stock of our principal raw materials and we will receive alarms through enterprise resource planning ("**ERP**") system if there is any shortage.

Our products are typically sold on a first-in-first-out basis. To minimize the risk of inventory backlogs, we conduct monthly, quarterly and annual reviews of our inventory levels. We also carry out physical stock counts and stock inspections from time to time to identify damaged products or obsolete products, which are disposed of or for which provisions are made.

During the Track Record Period, we did not experience any material shortage of inventory.

QUALITY CONTROL

We have a quality management department that devotes significant resources to quality management of our products. We have our own quality control system and devote significant attention to quality control for the designing, R&D manufacturing, testing and transportation of our products and product candidates. Our management team is actively involved in setting quality policies and managing our internal and external quality performance. We have established a strict quality control system in accordance with NMPA regulations, ISO13485 standards and EU regulations on the quality management system of medical devices, including MDD 93/42/EEC and IVD 98/79/EEC and related amended directives.

As of the Latest Practicable Date, our quality management department consisted of 27 employees. The department is divided into a quality system team, product quality team and R&D quality team. Our quality system team is responsible for setting up quality management system in compliance with applicable regulations and industry standards and also in charge of post-market surveillance for the global sales of our products. Our product quality team is further divided into a quality control team and quality assurance team. The quality control team is responsible for inspecting raw materials, production process and the quality of finished goods, while quality assurance team focuses on the implementation and maintenance of our quality management system, as well as monitoring our operation in real time throughout the entire production process to ensure its compliance with our quality management system. Our R&D quality team is responsible for the implementation of our quality management system throughout the R&D process and make sure the product and process under development is compliant with application regulations and industry standards.

Quality Control of Raw Material Supply

Prior to entering into supply agreements with our raw material suppliers, we perform background checks on the operating history, track record and market reputation of a list of potential suppliers, procure different product samples from the potential suppliers for inspection, if needed, and testing by our quality management department, conduct site visits and examine the production facilities of the potential suppliers to help ensure that the suppliers that we select meet our quality requirements, if applicable.

For our principal raw materials, suppliers are obligated to take measures to comply with our quality control standards for their products and production process. We are entitled to conduct on-site audits at the suppliers' premises to monitor their compliance with agreed quality assurance actions, which may be effected in the form of system, process or product audits. We also conduct off-site information assessments to evaluate the suppliers' performance. Traceability of the raw material supplies is required for our principal suppliers. Upon receiving supplies, we retain the right to reject or return based on our inspection and examination results.

Quality Control of Inventory

Our quality management department and our warehouse personnel take responsibilities and collaborate to help ensure the quality of our raw materials and products inventory. The quality management department is in charge of inspecting and examining raw materials and products before they are accepted as inventory.

The warehouse personnel is responsible for recording the inventory to ensure the traceability of our raw materials and products, the regular storage, maintenance and inspection of the inventory and warehouse maintenance. Designated warehouse personnel inspect the inventory on a regular basis according to the required storage and maintenance conditions of relevant inventory.

Quality Control of Design and Development

All the procedures of our design and development activities must strictly follow our design and development control policy and procedures, which specifically lists the stages to develop a new product. As discussed in the section headed "—Research and Development—Product Design" above, the project team for each project consists of representatives from various departments who contribute to our R&D work in their respective expertise fields. At the same time, the project team strictly follows each step of our internal protocol, and the design and development committee closely monitors and reviews key stages along the design and development process.

Quality Control for Manufacturing

Our quality management department is responsible for ensuring that we comply with applicable regulatory and industry standards throughout the entire manufacturing process through regular on-site inspections. After completing each step of the production process, we perform cleaning and maintenance procedures to prevent contamination or cross contamination before we proceed to the next production cycle. In addition, we perform regular dust and microbiological testing in our production facilities in accordance with our detailed manufacturing standards.

Each batch of our products is subject to a strict sample inspection before sales. We conduct sample testing on certain work in progress and semi-finished products at particular stages of production. In addition, our quality control team inspects the documentation relating to product quality, including its batch records, laboratory control records, production process records and other information that may impact product quality. Thereafter, they conduct a final review on all documents and determine whether a specific product can be released for shipment. Products that do not meet our quality standards are destroyed or otherwise disposed of in accordance with the relevant environmental control requirements.

After-Sale Quality Control

We are able to track our products sold to our end customers. We analyze feedback from our distributors and hospitals and handle any customer complaints with respect to the quality of our products. Quality complaints, both verbal and written, are documented and investigated pursuant to standard procedures. We have dedicated employees responsible for responding to complaint calls.

If any product falls short of the relevant quality standards, we will replace the defective product at our own costs. During the Track Record Period and up to the Latest Practicable Date, we did not experience any product returns or product liability claims.

INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are important to our business. Our future commercial success depends, in part, on our ability to obtain and maintain patents and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we owned 69 issued patents and pending patent applications. We had 20 issued patents and 31 pending patent applications in China. We also had one issued overseas patent, seven overseas patent applications and ten international patent applications under the PCT. We had 12 issued patents (ten in China, one in EU and one under the PCT) and 13 pending patent applications (ten in China and three under the PCT) in respect of our Core Product.

We acquire patents through self-development. As of the Latest Practicable Date, we self-owned all of our patents as well as patent applications and had no co-own or co-share arrangements of our patents and patent applications with third parties.

The table below lists the portfolio of material patents and patent applications of which we are the registered owner by product as of the Latest Practicable Date:

Product	Name of Patent	Components	In-review/Approval Number	Expiration Date	Covered Region	Status
Equil Patch Insulin Pump System	A wireless communication system for patch insulin pump systems	Wireless communication system	201210104999.5	April 10, 2032	China	Granted
	A connection mechanism for connecting a patch insulin pump and a base plate	Shell structure	201210111391.5	April 15, 2032	China	Granted
	A structure for connecting a patch insulin pump and a drug reservoir	Shell structure	201210180697.6	June 3, 2032	China	Granted
	An individualized insulin pump configuration optimization system based on cloud-based big data	Closed loop system	201710947229.X	October 11, 2037	China	Granted
	A method for controlling the infusion of insulin pump	Infusion set	202010093449.2	February 13, 2040 (if granted)	China	Pending
	Needle aids and medical systems including needle aids	Needle aids and medical system	PCT/CN2020/116839	–	Pending PCT national phase entry	Pending
	A method for controlling the infusion of insulin pump	Controlling method	PCT/CN2020/135161	–	Pending PCT national phase entry	Pending
AiDEX CGMS	A preparation method of electrochemical sensor with surface-cured polypeptide probe	Sensor	201610756537.X	August 28, 2036	China	Granted
	An electrochemical analyte sensing system and method capable of self-correcting interference signals	Sensing system	201610792337.X	August 30, 2036	China	Granted

Product	Name of Patent	Components	In-review/Approval Number	Expiration Date	Covered Region	Status
	An intelligent real-time dynamic blood glucose monitoring system and method based on cloud-based big data	Monitoring system	201710947227.0	October 11, 2037	China	Granted
	Needle aids and medical systems including needle aids	Needle aids	201911071063.5	November 4, 2039 (if granted)	China	Pending
	Triblock copolymers for implantable biosensor and their application and preparation method	Sensor	202010192423.3	March 18, 2040 (if granted)	China	Pending
	A glucose electrochemical sensor and its preparation method	Sensor	202010832447.0	August 17, 2040 (if granted)	China	Pending
	Biosensing systems having biosensors coated with co-polymers and their uses thereof	Sensing system	WOCN19085200	–	the European Union, Canada, Germany, Spain	Pending
	Biosensors coated with co-polymers and their uses thereof	Sensor	WOCN19085198	–	Canada, the European Union	Pending
	Implantable monitoring device calibration methods, sensor components and blood glucose monitoring systems	Calibration method, sensor and monitoring system	PCT/CN2020/130643	–	Pending PCT national phase entry	Pending
	Triblock copolymers for implantable biosensor and their application and preparation method	Sensor	PCT/CN2020/135162	–	Pending PCT national phase entry	Pending
	Cloud big data-based smart real time dynamic blood sugar monitoring system and method	Monitoring system	EP18867137	–	Europe	Pending

We consider that the key aspects of our Core Product include the physical package implementation (patch pump, reservoir, wireless portable diabetes assistant and infusion set), the specific attachment methods, the wireless communication protocol, and the cloud data implementation. We believe that our patents have covered all of the key aspects of our Core Product. As of the Latest Practicable Date, we had 12 granted patents in relation to our Core Product. The pending patent applications of Equil Patch Insulin Pump System listed in the table above are related to certain innovative features of the relevant components that are under development while we have obtained patent protections for such existing components deployed in the commercialized version of Equil. Given that obtaining pending patents is not a prerequisite for our future R&D activities and operations, we do not expect our pending patent applications to impose barriers on our current commercial expansion plans of our products in China and other jurisdictions. Even if we fail to register any patent that we are applying for, we will still be able to commercialize the relevant products, although without the protection of the relevant intellectual property right offered by patents during such patents' validity period. Therefore, we believe any failure to register the patents we are applying for will not have an immediate material adverse impact on our business, financial condition or results of operations. However, the validity of issued patents, patentability of pending patent applications and applicability of any of them to our products may be lower in priority than third-party patents issued on a later date if the application of third-party patents is filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. In addition, if any of the patent applications is rejected, we may lack patent protection covering the relevant aspects of our products. If any of the above circumstances occurs, our business, financial condition and prospects could be materially and adversely affected. See "Risk Factors—Risks Relating to Our Intellectual Property Rights—If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us."

The term of an individual patent may vary based on the countries/regions in which it is granted. In China and most other countries and regions in which we file patent applications, the term of an issued patent for invention is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. 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 issue 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 or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

We may rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors. We have entered into confidentiality agreements and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we use to employ our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee's work.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/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 sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. See "Risk Factors—Risks Relating to Our Operations—Our internal computer systems may fail or suffer security breaches."

We also own a number of registered trademarks and pending trademark applications. As of the Latest Practicable Date, we had registered trademarks for our Company and our corporate logo in China and other jurisdictions and are seeking trademark protection for our Company and our corporate logo in other jurisdictions where available and appropriate.

As of the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceedings or claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent. Our Directors confirm that they are not aware of any legal, arbitral or administrative proceedings of infringement of any third parties' intellectual property rights by us as of the Latest Practicable Date. For details, see "Appendix VI—Statutory and General Information—Further Information about Our Business—Intellectual Property Rights." For risks related to intellectual property rights, see "Risk Factors—Risks Relating to Our Intellectual Property Rights."

COMPETITION

The market in which we operate is characterized by rapid changes resulting from technological advances and scientific discoveries. In addition, it is subject to changes in the overall healthcare industry in China and globally. While we believe that our product development experience and R&D capabilities provide us with competitive advantages, we face potential competition from various sources, including major international medical device companies as well as domestic medical device manufacturers which are also developing insulin pumps, CGMS, artificial pancreas and other diabetes management medical devices.

We compete primarily on the basis of our products' proven track record of efficacy and safety, our first-mover advantage in the Chinese market, brand recognition among hospitals and physicians and the level of technical support and training we provide to physicians. We believe that our continued success depends on our ability to (i) innovate and develop advanced technology; (ii) apply our technology across product lines; (iii) develop a diverse portfolio of proprietary products; (iv) maintain our efficient operating model; (v) attract and retain skilled personnel; (vi) maintain high quality standards; (vii) obtain and maintain regulatory approvals; and (viii) effectively market our products.

Several of our competitors have significantly greater financial and other resources and may have longer track records and greater expertise in R&D, clinical trial, obtaining regulatory approvals and commercialization of approved products and may enjoy wide brand name recognition globally. Mergers and acquisitions in the medical devices industry may result in even more resources being concentrated among a small number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies or products complementary to, or necessary for, our products.

Our competitors dedicate, and we believe they will continue to dedicate, significant resources to promote their products aggressively. They may develop technologies and products that are safer, more effective, easier to use or less expensive than ours. They may also obtain FDA, NMPA or other regulatory approval for their products earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position ahead of us. We may encounter physicians, especially in the global market, who are committed to or prefer the products offered by our competitors due to existing relationships with our competitors. Any of these events could reduce or eliminate our commercial opportunities.

For competitive landscape of our products and product candidates, see "—Our Products and Product Pipeline" and "Industry Overview."

EMPLOYEES

As of the Latest Practicable Date, we had 438 employees in total. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number
Manufacturing	140
Sales and Marketing	135
Product Development	93
Quality Control	27
General and Administrative	43
Total	438

Substantially all of our employees are stationed in China. In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. These employment contracts typically have terms of three years.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries and stock incentive plans to our employees, especially our key employees.

We require all of our employees, especially those who involved in sales and marketing and business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We closely monitor our employee's compliance with anti-bribery and anti-corruption policies.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes, labor disputes or industrial action which had a material effect on our business, and we consider our relations with our employees to be good. As of the Latest Practicable Date, save as disclosed in "—Legal Proceedings and Compliance," we had complied with statutory social security insurance fund and housing fund obligations applicable to us under applicable laws in all material respects.

Employment Agreements with Key Management and R&D Staff

We normally enter into standard confidentiality, non-compete employment agreements with our key management and R&D staff. The non-compete agreement typically prohibits the employee from competing with us, directly or indirectly, during his or her employment and for at least two years after the termination of his or her employment. The agreements also typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment. For further details regarding the terms of confidentiality and employment agreements with our key management, see "Directors, Supervisors and Senior Management."

Our employees are represented by relevant labor unions. We believe that we maintain good working relationships with our employees and we did not experience any significant labor disputes or any significant difficulty in recruiting staff for our operations during the Track Record Period and up to the Latest Practicable Date.

INSURANCE

We maintain insurance policies covering our property and equipment that we believe are sufficient in accordance with customary industry practice. We do not carry any product liability insurance or business interruption insurance in China. See "Risk Factors—Risks Relating to Our Operations—Our insurance coverage may not completely cover the risks related to our business and operations" for further details of risk relating to our current insurance coverage. To minimize our product liability risk, we have instituted quality control measures in order to avoid or reduce the incidence of product defects. See "—Quality Control" above for further details of our quality control system.

PROPERTIES AND FACILITIES

We are headquartered in Hangzhou, Zhejiang province, China, with an aggregate area of approximately 20,000 sq.m. in use. This include approximately 15,000 sq.m., including a 1,500 sq.m. ISO Class 7 clean-room space and an 80 sq.m. ISO Class 8 clean-room space, for the production and pre-delivery inspection of our products. We own all of our production facilities and workshops. As of the Latest Practicable Date, none of our owned properties were subject to any encumbrance, mortgage, lien or pledge. We have obtained the building ownership certificates and the related land use right certificates for all of our owned properties which had been put into production and use.

We do not engage in any property activities as defined in Rule 5.01 of the Listing Rules. We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of April 30, 2021. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 38(1) of the Companies

(Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our Group's interests in land or buildings.

We rent an office with an aggregate area of approximately 120 sq.m. in Shanghai, China. The lease agreement provides a duration of two years. As of the Latest Practicable Date, we had not registered the lease agreement with the competent PRC authorities. As advised by our PRC Legal Advisor, failure to complete the registration of such lease agreement may lead to a fine ranging from RMB1,000 to RMB10,000 imposed by the relevant PRC authorities.

ENVIRONMENTAL PROTECTION, OCCUPATIONAL HEALTH AND SAFETY

Environmental, Social and Governance Matters

We believe our continued growth rests on integrating social values into our business. Since our establishment, we have been dedicated to creating a lasting positive environmental, social, and governance ("**ESG**") impact on our customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities and are aware of the climate-related issues that may have impact on our business. We are committed to complying with ESG reporting requirements upon [**REDACTED**].

Governance on ESG Matters

Our Board has the overall responsibility for overseeing and determining the environmental-related, climate-related and social-related risks and opportunities impacting the Company, establishing and adopting the ESG policy, strategies and targets of the Company, and reviewing the Company's performance against ESG-related targets and revising the ESG strategies as appropriate if significant variance from the target is identified. Our management team is generally responsible for carrying out the ESG policies in executing the Company's business operations.

We will establish an ESG oversight committee ("**ESG Oversight Committee**") at our management level upon [**REDACTED**], which will have a specific focus on environmental matters, such as waste management and recycling efforts, energy consumption, pollutants/green house gas emissions and reporting. The ESG Oversight Committee will be responsible for the identification, assessment and management of material ESG-related matters, including climate-related risks, by taking into consideration any metrics and targets stipulated in applicable laws, regulations and industry standards, including pollutants/greenhouse gas emissions, water and electricity consumption, among others. We will also take environmental protection as an important part in employee training, and continue to raise the awareness of energy conservation and environmental protection of all employees in the Group, helping us achieve a green, healthy and sustainable development.

Impact of ESG-related risks

We are subject to various environmental protection laws and regulations, the implementation of which involves regular inspection by local environmental protection authorities. Our operations involve the use of hazardous and flammable chemical materials. Our operations also produce such hazardous waste. We generally contracted qualified third-party sanitation or recycling companies for special treatment of our hazardous waste. For the years ended 2019 and 2020 and the four months ended April 30, 2021, we had incurred cost of maintaining compliance with applicable environmental rules and regulations of approximately RMB15.0 thousand, RMB89.9 thousand and RMB9.6 thousand, respectively. During the Track Record Period, we were not subject to any material claims, lawsuits, penalties or administrative actions which had a material and adverse effect on our business, financial condition or results of operations relating to noncompliance with applicable PRC environmental and occupational health and safety laws and regulations.

Growing concerns about climate change and greenhouse gas emissions have led to the adoption of various regulations and policies. The estimated magnitude of resulting impacts is evaluated over short, medium and long term horizons. In recent years, changing weather patterns due to climate change have increased in frequency of extreme weather conditions. Disasters created by extreme conditions could cause significant damage to or destruction of our facilities, resulting in temporary or long-term closures of our facilities and operations and significant expense for repair or replacement of damaged or destroyed facilities. In the medium to long term, increasingly enacted legislation and regulations in response to potential impacts of climate change may have the potential to impact our operations directly or indirectly as a result of required compliance by our customers or our supply chain, and may subject us to additional costs and restrictions, including increased energy and raw materials costs and pollutant discharge costs, which could negatively impact our financial condition and results of operations. Any inconsistency of such laws and regulations may also affect our costs of compliance.

Occupational Health and Safety

We are subject to various occupational health and safety laws and regulations. During the Track Record Period, we stored hazardous and flammable chemical materials required for and generated in our production and operation process in dedicated warehouses and marked with special warning signs. During the Track Record Period, we had not experienced any material accidents at our manufacturing facilities.

We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. Our employees responsible for manufacturing and quality control and assurance are required to hold relevant qualifications, as well as wear the proper safety gear when working. We conduct regular safety inspections and maintenance for our manufacturing facility.

If we breach any environmental-related laws and regulations, or faces any accusation of negligence in environmental protection, in addition to the potential fines and penalties, such incidents may also adversely affect our business operation and financial position. See "Risk Factors—If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business."

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global medical devices markets, our ability to develop, manufacture and commercialize our products and product candidates, and our ability to compete with other medical device companies. For details of various risks and uncertainties we face, see "Risk Factors." We also face various financial risks. In particular, we are exposed to credit, liquidity, and foreign exchange risks that may arise in the normal course of our business.

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. Our Audit Committee and ultimately our Directors supervise the implementation of our risk management policies. 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.

The following key principles outline our Group's approach to risk management and internal control:

Our senior management oversees and manages the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operations and our management's handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group.

Our legal and internal audit personnel are responsible for developing and implementing our risk management policy and carrying out our day-to-day risk management practice, such as assessing risks on key business operations, advising risk responses and optimizing risk management policies. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (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 objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Intellectual Property Rights Risk Management

Compliance with applicable PRC and overseas laws and regulations, especially laws and regulations governing the protection of our intellectual property rights and the prevention of liabilities resulting from potential illegal content of publication and intellectual properties infringement are major focus areas of our operational risk management. Our legal department is responsible for approving contracts, monitoring any changes in the applicable laws and regulations and ensuring the ongoing compliance of our operations with the applicable law and regulations.

Our intellectual property department assists in conducting searches to help ensure that all of our intellectual property is under the protection of relevant laws and regulations, and also helps ensure the application for trademark, copyright or patent registrations for, as well as filing with relevant authorities of all of our products. The intellectual property department shall then administer the execution process of obtaining the necessary filings, approvals, and/or licenses. Other than some standard contracts which have been reviewed and adopted by the legal department, all the contracts of our Company are required to be reviewed and approved by our legal department prior to execution. In addition, we establish policies for intellectual property infringement notices to help ensure timely monitoring the infringement incidents.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. During the Track Record Period, we regularly reviewed and enhanced our internal control system. As of the Latest Practicable Date, there were no material outstanding issues relating to our Groups internal control. 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 each aspect of our operations, such as protection of intellectual property, environmental protection and occupational health and safety. We provide periodic training on these measures and procedures to our employees as part of our employee training program. We also regularly monitor the implementation of those measures and procedures through our on-site internal audit team for each stage of the produce development process.

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

- We have established the Audit Committee which shall (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 the risk management and internal control procedures of our Group. For more details, see "Directors, Supervisors and Senior Management—Board Committees—Audit Committee."

- We have engaged Orient Capital (Hong Kong) Limited as compliance adviser upon [**REDACTED**] to provide advice to our Directors and management team until the end of the first fiscal year after the [**REDACTED**] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of the [**REDACTED**] from the [**REDACTED**] complies with the section entitled "Future Plans and Use of [**REDACTED**]" in this Document after the [**REDACTED**], as well as to provide support and advice regarding the requirements of relevant regulatory authorities in a timely fashion.

- We will engage a PRC legal adviser to advise us on and keep us abreast with PRC laws and regulations after the [**REDACTED**]. We will continue to arrange various training to be provided by external legal advisors from time to time when necessary and/or any appropriate accredited institution to update our Directors, Supervisors, members of our senior management and relevant employees on the latest applicable laws and regulations.

- We maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities. In particular, we require distributors to provide written commitments to us which stipulates our requirements for various aspects of distributors' operations, such as prohibiting distributors from providing any form of improper benefits and require distributors to enter into distributorship agreements with any sub-distributors they engage to have such sub-distributors abide by our policies. We also monitor our sales and marketing personnel to ensure their compliance with applicable promotion and advertising requirements, which include restrictions on promoting our products for unapproved uses or patient populations, also known as off-label use, and limitations on industry-sponsored scientific and educational activities. In particular, each of sales and marketing personnel is required to undertake to us in writing that they will restrain themselves from any bribery and/or any other improper business practices.

- We maintain a comprehensive treasury policy, detailing specific functions and internal control measures for capital use. These functions and measures include but are not limited to procedures of capital management, separation of capital management responsibilities, liquidity management and follow-up and analysis of the implementation of capital plan.

- Our Directors believe that compliance creates value for us. We are dedicated to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behavior across our Group, we conduct regular internal compliance checks and inspections, adopt strict accountability internally and conduct compliance training.

- We will comply with the Corporate Governance Code. We have established four board committees, namely, the Audit Committee, the Remuneration and Assessment Committee, the Nomination Committee and the Strategy Committee, with respective terms of reference in compliance with the Corporate Governance Code. For details, see "Directors, Supervisors and Senior Management."

- We have adopted internal protocols governing both the confidentiality and privacy for patient sample and data. There is written operation procedures in place for sample/data collection, test procedures, data storage as well as data access. Such data access is on an as-needed basis for internal employees, and external access is not allowed and requires written approvals from the head of the quality control/compliance department.

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

We may be involved in legal proceedings in the ordinary course of business from time to time. During the Track Record Period and up to the Latest Practicable Date, none of us or our Directors were involved in any litigation, arbitration or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened material litigation, arbitration or administrative proceedings against us or any of our Directors, which individually or in the aggregate would have a material adverse effect on our business, financial condition or results of operations.

Compliance

During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance incidents which our Directors believe would, individually or in the aggregate, have a material operational or financial impact on our business as a whole. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had complied with the applicable laws and regulations in all material respects, except for the non-compliance which would not have a material adverse effect on our business as a whole.

During the Track Record Period and as of the Latest Practicable Date, we did not make full contributions to the social insurance and housing funds for certain employees in accordance with the relevant PRC laws and regulations. During the Track Record Period and as of the Latest Practicable Date, we engaged third-party human resources agencies to pay social insurance and housing funds for certain employees, primarily due to the preference of such employees to participate in local social insurance and housing fund schemes in their place of residency. Under the agreements entered into between such third-party human resources agencies and us, the third-party human resources agencies have the obligations to pay social insurance premium and housing funds for our relevant employees. If the human resource agencies fail to pay the social insurance or housing fund contributions for our employees as required under applicable PRC laws and regulations, we may be subject to penalties imposed by the local social insurance authorities and the local housing fund management centers for failing to discharge our obligations in relation to payment of social insurance and housing funds as an employer. These third-party human resources agencies have confirmed in writing that they have paid such contributions in compliance with applicable PRC laws and regulations. As of the Latest Practicable Date, we had not received any administrative penalty or labor arbitration application from employees for our agency arrangement with third-party human resources agencies.

Pursuant to relevant PRC laws and regulations, the relevant PRC authorities may demand us to pay the outstanding social insurance contributions within a stipulated deadline and we may be liable to a late payment fee equal to 0.05% of the outstanding amount for each day of delay. If we fail to make such payments, we may be liable to a fine of one to three times the amount of the outstanding contributions. With respect to a failure to pay the full amount of housing funds as required, the housing funds management center in China may require payment of the outstanding amount within a prescribed period. If the payment is not made within such time limit, an application may be made to the PRC courts for compulsory enforcement. See "Risk Factors—Risks relating to doing business in China—We may be subject to penalties under relevant PRC laws and regulations due to failure to be in full compliance with social insurance and housing funds regulation."

Our Directors believe that such non-compliance would not have a material adverse effect on our business or results of operations, considering that: (i) we had not been subject to any administrative actions, fines or penalties during the Track Record Period and up to the Latest Practicable Date due to such non-compliance; (ii) as of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing funds; (iii) we were neither aware of any employee complaints filed against us nor involved in any labor disputes with our employees with respect to social insurance and housing funds during the Track Record Period and up to the Latest Practicable Date; and (iv) as advised by our PRC Legal Advisor, considering relevant regulatory policies and the facts stated above, such non-compliance will not have a material adverse effect on our financial condition or results of operations as a whole and the [**REDACTED**]. We made provisions of RMB2.9 million as of April 30, 2021 in connection with the shortfall amount of the social insurance and housing provident fund contribution during the Track Record Period.

We plan to make full payment of social insurance and housing provident fund contributions as soon as possible in compliance with relevant PRC laws and regulations. We have enhanced our internal control measures, including implementing a policy on social insurance and housing provident fund contribution in compliance with relevant PRC laws and regulations. In addition, we have designated our human resources department to review and monitor the reporting and contributions of social insurance and housing provident fund and we will consult our PRC legal counsel on a regular basis for advice on relevant PRC laws and regulations to keep us abreast of relevant regulatory developments.

IMPACT OF COVID-19 OUTBREAK

Since December 2019, a novel strain of coronavirus or COVID-19, has become widespread in China and around the world. To contain the virus' spread, China and many other countries have taken various restrictive measures, such as lockdowns, quarantines, closure of work places, travel restrictions and home office policies.

The following paragraphs describe the impact of COVID-19 on major aspects of our business and operations.

- *Clinical trials and regulatory affairs.* In response to the COVID-19 pandemic, hospitals and physicians across China focused their efforts on treating COVID-19 patients and prioritized resources toward containing the virus, resulting in our clinical trial of AiDEX G7 in China being delayed for around four months. Nonetheless, the COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We have not experienced and currently do not expect any material disruptions in regulatory affairs with respect to our overall development plans due to the COVID-19 pandemic. We also adopted various measures, such as cooperating with clinical trial sites to offer personal protection equipment such as masks to our enrolled patients, engaging in frequent communications with our principal investigators to identify and address any issues that may arise, suggesting the investigators to communicate with the enrolled patients on visiting local qualified hospitals for follow-up evaluations if necessary.

- *Sales and marketing activities.* During the COVID-19 outbreak, reduced transportations and social distancing policies have affected the organization of conferences, seminars and other offline sales and marketing activities, in particular, interactions with overseas clients. As a result, the demand for our products in China and overseas decreased, which adversely affected our financial performance in the first quarter of 2020.

- *Daily operations.* We followed the government's policy to prolong the Chinese Spring Festival leave. We had resumed full and normal operations since the end of February 2020. With COVID-19 pandemic gradually stabilized in China, our business started to recover and gradually resumed growth since the second quarter of 2020. To prevent any spread of COVID-19 in our offices and production facilities, we have implemented preventive measures such as regularly sterilizing and ventilating our offices and production facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees, and providing face masks and disinfectant to employees attending our offices and facilities. As of the Latest Practicable Date, we were not aware of any suspected or confirmed active COVID-19 cases on our premises.

- *Supplies of raw materials and services.* During the Track Record Period, we had not experienced any material disruption or shortage of supplies of our principal raw materials or any material suspension or termination of other services provided by third-party suppliers since the COVID-19 outbreak, and our suppliers had resumed normal operations as of the Latest Practicable Date.

- *Financial performance.* Despite the fact that our revenue increased by 45.1% from RMB51.9 million in 2019 to RMB75.3 million in 2020, based on our current estimate, our sales amount for the full year of 2020 would have been increased by 83.0% in 2020, as compared to the prior year, without taking into consideration the impact caused by COVID-19 outbreak.

As of the Latest Practicable Date, the COVID-19 pandemic had not been contained in Europe and thus our access to local markets and sales and marketing activities there were limited, which negatively impacted our market expansion and sales growth. Since July 2021, certain cities in China have been impacted by resurgences of COVID-19 which had reduced our on-site education activities in hospitals. We had gradually resumed these activities between the end of August and the beginning of September, following the control of such resurgences of COVID-19. The resurgence of COVID-19 caused a shortage of certain raw materials from July to August 2021. In response, we promptly secured alternative suppliers, and the supplies resumed normal by the end of August 2021. We have mobilized, and will continue to mobilize, internal and external resources and leveraged our operating capabilities to minimize the adverse effect on our business caused by the COVID-19 outbreak.

However, the extent to which the COVID-19 outbreak impacts our business, results of operations and financial condition will depend on many factors beyond our control, including the extent of resurgences of the disease and its variants, vaccine distribution and other actions in response to the virus or to contain its impact. It is uncertain when and whether COVID-19 could be contained globally. We are closely monitoring impact of COVID-19 outbreak on us and plan to continue implementing measures necessary to ease the impact of the outbreak on our operations. While we continue to assess the impact of the COVID-19 outbreak, we are unable to accurately predict the full impact of COVID-19. We cannot assure you that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results

of operations, financial condition or prospects. Our operations may also be adversely affected if any of our employees or employees of our distributors, suppliers and other business partners were suspected of contracting or contracted COVID-19. In addition, the commencement of new clinical trials for product candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. For more details, see "Risk Factors—Our operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks, in particular the COVID-19 outbreak."

LICENSES AND PERMITS

During the Track Record Period and as of the Latest Practicable Date, we had obtained all requisite licenses, approvals, certificates and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material licenses required for our operation in the PRC and overseas:

License/Permit	Holder	Grant Date	Expiration Date
Medical Device Production License (《醫療器械生產許可證》)	the Company	September 22, 2021	February 23, 2025
Registration Certificate for Class III Medical Device (《醫療器械註冊證》, No. 國械註准20173153333)	the Company	September 12, 2017	September 11, 2022
Registration Certificate for Class III Medical Device (《醫療器械註冊證》, No. 國械註准20173663330)	the Company	June 1, 2018	August 31, 2022
Registration Certificate for Class III Medical Device (《醫療器械註冊證》, No. 國械註准20173543312)	the Company	May 15, 2019	August 28, 2022
Registration Certificate for Class II Medical Device (《醫療器械註冊證》, No. 浙械註准20172400420)	the Company	April 25, 2017	April 24, 2022
Registration Certificate for Class II Medical Device (《醫療器械註冊證》, No. 浙械註准20172400509)	the Company	May 22, 2017	May 21, 2022
Registration Certificate for Class II Medical Device (《醫療器械註冊證》, No. 浙械註准20172400981)	the Company	September 6, 2017	September 5, 2022
Registration Certificate for Class II Medical Device (《醫療器械註冊證》, No. 浙械註准20172401051)	the Company	September 29, 2017	September 28, 2022
Registration Certificate for Class II Medical Device(《醫療器械註冊證》, No. 浙械註准20212220363)	the Company	August 24, 2021	August 23, 2026

License/Permit	Holder	Grant Date	Expiration Date
Record Certificate for II Medical Devices Operation (《第二類醫療器械經營備案憑證》)	the Company	November 25, 2020	N/A
Medical Devices Operation Permit (《醫療器械經營許可證》)	Hangzhou E-commerce	November 26, 2020	November 25, 2025
Record Certificate for II Medical Devices Operation (《第二類醫療器械經營備案憑證》)	Hangzhou E-commerce	November 25, 2020	N/A
Qualification Certificate for Internet Drug Information Services (《互聯網藥品資訊服務資格證書》)	Hangzhou E-commerce	December 28, 2020	April 26, 2025
Record Certificate for Internet Medical Devices Sales (《醫療器械網路銷售備案憑證》, No. (浙杭)網械企備字[2021]00024)	Hangzhou E-commerce	January 7, 2021	N/A
Record Certificate for Internet Medical Devices Sales (《醫療器械網路銷售備案憑證》, No. (浙杭)網械企備字[2021]00025)	Hangzhou E-commerce	January 7, 2021	N/A
Record Certificate for Internet Medical Devices Sales (《醫療器械網路銷售備案憑證》, No. (浙杭)網械企備字[2020]00545)	Hangzhou E-commerce	January 6, 2021	N/A
EC certificate for Medical Device, No. HD 1582538-1	MicroTech Medical	March 31, 2021	April 23, 2024
EC certificate for In Vitro Diagnostic Medical Device, No. HL 1582538-1	MicroTech Medical	March 31, 2021	April 23, 2024
Certificate of Quality Management System EN ISO 13485:2016	MicroTech Medical	March 31, 2021	April 23, 2023

We intend to initiate the renewal procedures for each of the above material licenses, approvals, certificates and permits at least six months prior to their expiration date. We will also apply for registration certificates once our product candidates are ready to be marketed. Our PRC Legal Advisor confirmed that as of the Latest Practicable Date, there was no legal impediment for us to renew the relevant licenses, approvals, certificates and permits as long as we comply with the relevant legal requirements.

AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and recognitions for which we received government grants as of the Latest Practicable Date:

Award and Recognition	Year of Award/Grant	Award/Grant Authority
Innovative Medical Device (insulin pump)	2018	The Ministry of Science and Technology of the PRC
Leading Innovation Team (intelligent cognitive computed based closed loop artificial pancreas)	2017	Leading Group for Talent Work of the CPC Zhejiang Provincial Committee
National Major Scientific Research Program in 13th Five-Year Plan Period (construction and application of cloud-based AI diabetes management platform for children and adolescents with diabetes)	2016	The Ministry of Science and Technology of the PRC
Made-in-Zhejiang Excellence	2016	Zhejiang Provincial Economic and Information Commission/Zhejiang Provincial Development and Reform Commission
Technology Innovation Project of Small and Medium-sized Enterprises (patch insulin pump system)	2014	The Ministry of Science and Technology of the PRC
Key Diabetes Diagnostics and Therapy Medical Device Research Center in Zhejiang Province	2014	The Government of Zhejiang Province
Major Science and Technology Program of Zhejiang Province (second-generation patch insulin pump system)	2014	Zhejiang Provincial Department of Science and Technology
Special Program for the Development of Information Service Industry in Zhejiang Province (cloud-based diabetes management platform)	2014	Zhejiang Province Economic and Information Commission