

Airdoc Technology (2251 HK)

Pioneer in AI-based medical imaging industry

As a pioneer in the field of AI based medical imaging market, Airdoc is leading the industry to offer solutions that integrate hardware, software, algorithms and service together as one product. We are bullish on China AI-based medical imaging market given the large pool of untapped patients for accurate AI-based diagnosis. We like Airdoc and initiate at BUY with DCF-based TP of HK\$95.32.

- Pioneer in AI-based medical imaging industry.** The Company has the first NMPA-approved Class III AI-empowered retina-based auxiliary diagnosis product in China, Airdoc-AIFUNDUS (1.0), which is an AI-based Software as a Medical Device (SaMD) providing solutions for auxiliary diagnosis of diabetic retinopathy. Airdoc has established a comprehensive vast database including approximately 3.7mn real-world user retinal images to enhance its algorithm. F&S forecasts the AI-based medical imaging market in China to reach RMB92.3bn in 2030E, mainly driven by 1) population aging and the increasing number of chronic diseases, 2) improving penetration rate in both medical and consumer healthcare environments, and 3) large unmet medical needs for accurate and effective AI-based diagnosis.
- Rich pipeline and multichannel commercialization strategy.** Besides Airdoc-AIFUNDUS (1.0), the Company has constructed rich pipeline in SaMD, such as AIFUNDUS (2.0) for diagnosis of hypertensive retinopathy, retinal vein occlusion and age-related macular degeneration (AMD), AIFUNDUS (3.0) for pathological myopia and retinal detachment. The AIFUNDUS (2.0)/ (3.0) is expected to apply for approval from NMPA by 2022E/ 2024E, respectively. As of Nov 2021, the Company commenced the multi-center clinical trial for AIFUNDUS (2.0). Airdoc's glaucoma detection SaMD received approval from the Shanghai branch of the NMPA in Jun 2020 and cataracts detection SaMD has submitted application to the NMPA in Apr 2021. In addition, Airdoc also developed health risk assessment solutions to address various healthcare needs including hospitals, community clinics, health checkup centers, insurance companies, optometry centers and pharmacies. Besides, the Company's fully automated fundus cameras, AIFUNDUSCAMERA-P, received Class II certificate from the Shanghai branch of the NMPA in Mar 2021, which significantly lowers the barriers for physicians to offer eye screening.
- Revenue to grow at a 112% CAGR in FY21E-23E.** We expect total revenue to grow at 148%/ 102%/ 89% YoY in FY21E/ 22E/ 23E and to reach RMB118mn/ RMB239mn/ RMB451mn in FY21E/ 22E/ 23E, mainly driven by the fast-growing sales from AI-based software solutions. We expect Airdoc to record RMB99mn/ RMB146mn/ RMB155mn attributable net loss in FY21E/ 22E/ 23E.
- Initiate at BUY with TP of HK\$95.32.** Given that Airdoc will mainly rely on future commercialization of AI-based software solutions, we believe DCF would be a reasonable method to value the Company. We derive TP of HK\$95.32 based on a 10-year DCF model (WACC:11.4%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue (RMB mn)	30	48	118	239	451
YoY growth (%)	N/A	57	148	102	89
Net income (RMB mn)	-87	-80	-99	-146	-155
EPS (RMB)	N/A	N/A	-0.95	-1.41	-1.50
Consensus EPS (RMB)	N/A	N/A	N/A	N/A	N/A
P/S (x)	116	74	30	15	8
P/B (x)	N/A	N/A	2	2	3
ROE (%)	N/A	-19	-6	-10	-12
Net gearing (%)	0.53	Net cash	Net cash	Net cash	Net cash

Source: PHIP, CMBIS estimates, Bloomberg

BUY (Initiation)

Target Price	HK\$95.32
Up/Downside	+131.35%
Current Price	HK\$41.20

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Mkt. Cap. (HK\$ mn)	4,267
Avg. 3mths t/o (HK\$ mn)	N/A
52W High/Low (HK\$)	74.95/40.50
Total Issued Shares (mn)	26

Source: Bloomberg

Shareholding Structure

Management and employee	30.76%
Fosun International	9.92%
Ping An Insurance	6.92%
Sogou Information	5.74%
Others	46.66%

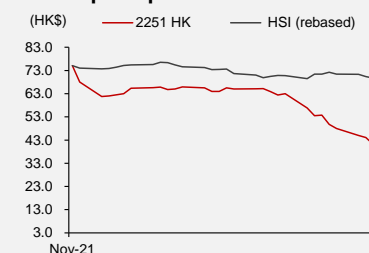
Source: HKEx, Bloomberg;
Note: As of 5 Nov 2021

Share performance

	Absolute	Relative
1-mth	-32.5%	-27.7%
3-mth	N/A	N/A
6-mth	N/A	N/A

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: KPMG

Web-site: <https://www.airdoc.com/>

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Investment thesis

Beijing Airdoc Technology Co., Ltd. (Airdoc) is one of the first to provide AI-empowered retina-based early detection, diagnosis and health risk assessment solutions in China. Leveraging retinal imaging, multimodal data analyses and AI deep learning algorithms, the Company's solutions differ from traditional chronic disease early detection and diagnosis, enabling non-invasive, accurate, fast, effective and scalable detection and diagnosis of chronic diseases in both medical institutions and consumer healthcare providers.

Pioneer in AI-based medical imaging industry

As China's market leader of AI-empowered retina-based diagnosis solutions which integrated software and hardware, in the past six years of operations, Airdoc has accumulated deep expertise and has developed deep learning algorithms that are broadly applicable to detect and diagnose a wide range of chronic diseases.

The Company's Airdoc-AIFUNDUS (1.0), an AI-based Software as a Medical Device (SaMD) approved for auxiliary diagnosis of diabetic retinopathy, was the first of its kind to obtain the Class III medical device certificate from the NMPA, enabling it to be used in hospitals in China to assist physicians with medical diagnoses.

Airdoc has accumulated a comprehensive, vast and diverse retinal image database which includes approximately 3.7mn real-world user retinal images with corresponding multimodal data, labelled by experienced medical experts and processed according to disease and lesion. Given the extensive associated costs and increasingly stringent data protection standards, the Company's extensive database has served as a key entry barrier for competitors. This database has served as the foundation for its continued development and optimization of deep learning algorithms to accurately pinpoint conditions related to chronic diseases, as well as its continued development of new generations of SaMDs and solutions targeting new indications and for wider applications in various scenarios.

Large opportunity in AI-based medical imaging market

Due to the aging population, chronic diseases, such as cardiovascular diseases and diabetes, have become the prevalent cause of death for people over 60 years old. Early detection and ongoing disease management are crucial to alleviate the burden of chronic diseases on patients, families and societies. However, the demand for such services has not been met due to the shortage of experienced physicians and the imbalanced allocation of medical resources.

AI-based medical imaging analysis offers promising solutions to address these unmet healthcare demands effectively and efficiently. AI-based retinal imaging analysis, in particular, enables a non-invasive, accurate, fast, effective and scalable solution because the retina is the only part of the human body where blood vessels and nerve cells can be directly viewed in a non-invasive manner. AI-based retinal imaging analysis is more widely applicable in both medical and consumer healthcare environments compared to other AI-based medical imaging solutions, which has brought the market for AI-based retinal imaging to the cusp of explosive growth.

F&S forecasts the AI-based medical imaging market in China will grow at a 76.7% CAGR from RMB0.3bn in 2020 to RMB92.3bn in 2030E, mainly driven by 1) population aging and the increasing number of chronic diseases, 2) improving penetration rate in both medical and consumer healthcare environments, and 3) large unmet medical needs for accurate and effective AI-based diagnosis.

AI-based medical imaging is used in medical institutions primarily to assist physicians with disease

detection and diagnoses, and accounts for approximately 86% of the AI-based medical imaging market in 2020. F&S forecasts AI-based medical imaging in medical institutions to grow at a 65.9% CAGR from 2020 to 2030E to RMB42.3bn in 2030E.

Due to the unmet needs of providing accessible and continuous health management solutions in consumer healthcare environments, AI-based medical imaging in consumer healthcare environments is a white space segment and is expected to experience faster growth compare to AI-based medical imaging in medical institutions. F&S forecasts AI-based medical imaging in consumer healthcare environments will grow at a 102.7% CAGR from 2020 to 2030E to RMB50.01bn in 2030E.

Rich pipeline to provide integrated software and hardware solutions

Airdoc has developed a pipeline of SaMDs and health risk assessment solutions to address various healthcare needs for the wider population. As of June 13, 2021, Airdoc's R&D team consisted of over 60 members with deep experience in AI-technologies and medicine. The Company has developed a robust IP portfolio covering key technologies for its software, hardware devices and algorithms, with 134 patents and patent applications in China and six published PCT applications.

Airdoc's Airdoc-AIFUNDUS (1.0) demonstrated an industry-leading sensitivity and specificity during clinical trial. Airdoc-AIFUNDUS (1.0) is a SaMD for auxiliary diagnosis of diabetic retinopathy approved by the NMPA as a Class III medical device. The Company is developing Airdoc-AIFUNDUS versions (2.0) and (3.0) to expand the indications to cover hypertensive retinopathy, retinal vein occlusion, age-related macular degeneration (AMD), pathological myopia and retinal detachment. As of Nov 2021, the Company commenced the multi-center clinical trial for AIFUNDUS (2.0).

Besides, Airdoc plans to rapidly advance the development and commercialization of its individual SaMDs, covering diseases such as glaucoma, cataracts, ICVD and ASCVD, gestational diabetic retinopathy, gestational hypertensive retinopathy, papilledema intracranial hypertensive retinopathy and anemia. Airdoc has obtained a Class II medical device registration certificate for its glaucoma detection SaMD in June 2020 from the Shanghai branch of the NMPA. Airdoc had submitted the Class II medical device registration certificate application for its cataracts detection SaMD in April 2021.

In addition, Airdoc also developed health risk assessment solutions to address various healthcare needs including hospitals, community clinics, health checkup centers, insurance companies, optometry centers and pharmacies. As of June 13, 2021, Airdoc had implemented its AI-based solutions in over 140 iKang health checkup centers. As of June 13, 2021, Airdoc has provided health risk assessment solutions to branches of insurance companies in 28 provinces. For optometry centers, Airdoc provides health risk assessment solutions to Nova Vision, a leading optometry chain in China, to provide a comprehensive analysis of customers' retinal environment and identify risk factors that may lead to impaired vision, which help optometry centers raise awareness for eye health, especially in younger populations. As of June 13, 2021, the Company's health risk assessment solutions covered over 740 optometry centers and are expected to cover 1,200 stores by end-2021.

As of hardware adaptability, the Company's AI-based SaMDs are compatible with most fundus cameras on the market. However, its in-house developed hardware devices powered by on-device AI technologies provide an improved user experience.

Besides, the Company's fully automated fundus cameras, AI-FUNDUSCAMERA-P, received Class II certificate from NMPA in Mar 2021, which significantly lower the barriers for physicians to offer eye screening. Its AI-FUNDUSCAMERA-D, which is currently at research and development stage, is a desktop fundus camera with comparable image quality but significantly lower costs than traditional high-end desktop fundus cameras. Its AI-FUNDUSCAMERA-M is a multimodal health scanner in the research and development stage.

Revenue to grow at a 112% CAGR in FY21E-23E

We expect total revenue to grow 148%/ 102%/ 89% YoY to RMB118mn/ RMB239mn/ RMB451mn in FY21E/22E/23E, mainly driven by the fast-growing in provisions of AI-based software solutions.

Airdoc recorded net losses of RMB87mn/ RMB80mn in FY19A/20A. We expect it to continue incur net loss of RMB99mn/ RMB146mn/ RMB155mn in FY21E/FY22E/FY23E.

Initiate at BUY with TP of HK\$95.32

Given that Airdoc will mainly rely on future commercialization of AI-based software solutions, we believe DCF would be a reasonable method to value the Company. We derive TP of HK\$95.32 based on a 10-year DCF model (WACC:11.4%, terminal growth rate: 3.0%).

Investment risks

- 1) Future growth depends substantially on the success of its product portfolio;
- 2) Limited experience in marketing and sales;
- 3) Reliance on a limited number of major customers;
- 4) Supply reliance on third-party OEM.

Leader in AI-based medical imaging market

Founded in 2015, Beijing Airdoc Technology Co., Ltd. (Airdoc) is one of the first to provide AI-empowered retina-based early detection, diagnosis and health risk assessment solutions in China. Leveraging retinal imaging, multimodal data analyses and AI deep learning algorithms, the Company's solutions differ from traditional chronic disease early detection and diagnosis, enabling non-invasive, accurate, fast, effective and scalable detection and diagnosis of chronic diseases in both medical institutions and consumer healthcare providers.

Figure 1: Major milestones of Airdoc

Year	Event
Sep 2015	Airdoc was established in Beijing.
Sep 2017	Airdoc hosted the first international medical AI conference sponsored by the Chinese Association for Artificial Intelligence (中国人工智能学会).
Apr 2018	Airdoc started the strategic cooperation with iKang.
Jun 2018	Airdoc started the strategic cooperation with Nova Vision.
Sep 2018	Airdoc entered into a project cooperation agreement with Zhongshan Ophthalmic Center of Sun Yat-sen University regarding the development of AI assessment and diagnosis system.
Oct 2019	Airdoc obtained the Wu Wen Jun AI Science and Technology Progress Award — Enterprise Technology Innovation Engineering Project.
Jun 2020	Airdoc received a Class II medical device registration certificate from the Shanghai branch of the NMPA for glaucoma detection SaMD.
Aug 2020	Airdoc obtained a Class III medical device registration certificate from NMPA for Airdoc-AIFUNDUS (1.0).
Dec 2020	Airdoc was converted into a joint stock company.
Mar 2021	Airdoc received a Class II medical device registration certificate from the Shanghai branch of the NMPA for AI-FUNDUSCAMERA-P.
May 2021	Airdoc completed Series D Financing.

Source: PHIP, CMBIS

Airdoc, leveraging its proprietary AI-based solutions, extensive real-world database, comprehensive software and hardware product offerings, multi-channel commercialization pathways and deep industry and regulatory understanding, has developed and established high entry barriers as a first mover in the industry.

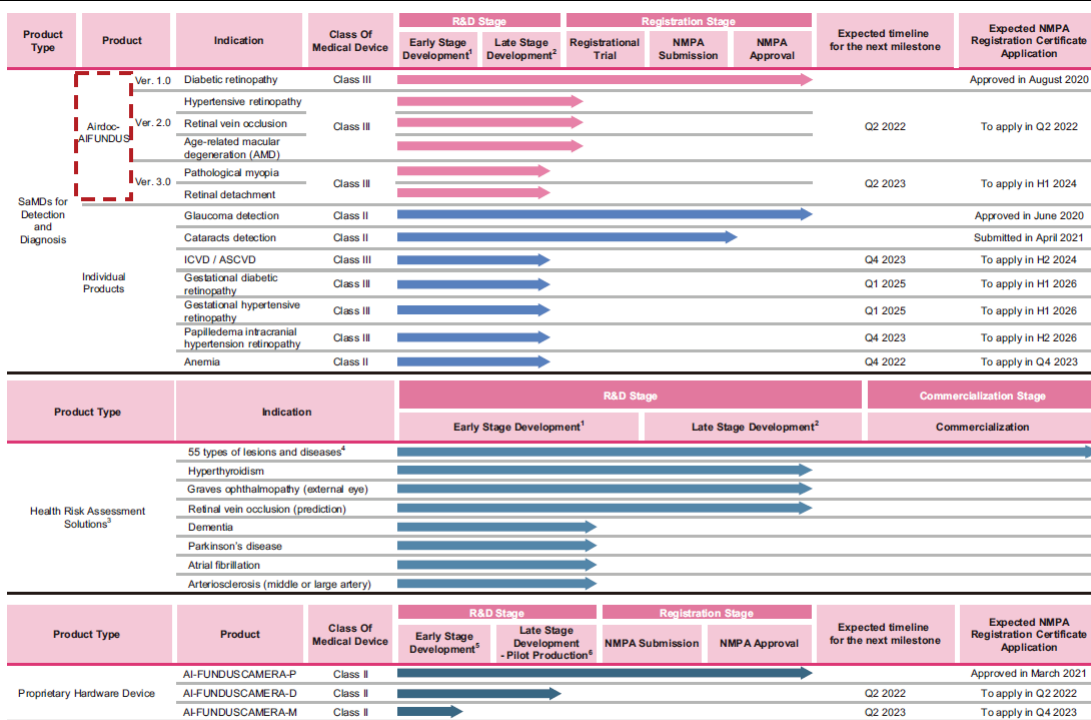
Airdoc's portfolio includes SaMDs for detection and diagnosis, health risk assessment solutions and hardware devices, forming an integrated solution.

SaMDs for detection and diagnosis. In August 2020, Airdoc obtained the Class III medical device certificate for Airdoc-AIFUNDUS (1.0), which is a SaMD for auxiliary diagnosis of diabetic retinopathy. Airdoc is currently expanding the indications in Airdoc-AIFUNDUS (2.0) to cover hypertensive retinopathy, retinal vein occlusion and AMD and Airdoc-AIFUNDUS (3.0) to cover pathological myopia and retinal detachment. Separately, Airdoc has developed and is developing other SaMDs for glaucoma, cataracts, ICVD and ASCVD, gestational diabetic retinopathy, gestational hypertensive retinopathy, papilledema intracranial hypertension retinopathy and anemia.

Health risk assessment solutions. Health risk assessment is a white space segment, due to greater difficulty in predicting the risk of developing a chronic disease compared to detection or diagnosis of an existing disease. Airdoc offers health risk assessment solutions with the ability to detect risk indicators. The Company has marketed its health risk assessment solutions to a wide range of customers in various healthcare settings. Airdoc also plans to expand the coverage of diseases and lesions of its health risk assessment solutions.

Hardware devices. Airdoc has three intelligent, fully automated hardware devices with AI technology in its portfolio to optimize image collection for subsequent analysis with its SaMDs. Airdoc’s AI-FUNDUSCAMERA-P is a portable, fully automatic and fully self-service fundus camera and it has received a Class II medical device registration certificate in March 2021. Its AI-FUNDUSCAMERA-D, which is currently at research and development stage, is a desktop fundus camera with comparable image quality but significantly lower costs than traditional high-end desktop fundus cameras. The Company aims to apply for a Class II medical device registration certificate in the second quarter of 2022E. Its AI-FUNDUSCAMERA-M, a multimodal health scanner, is in the research and development stage. Airdoc expects to apply for a Class II medical device registration certificate in the fourth quarter of 2023E.

Figure 2: Development status of Airdoc’s portfolio



Our Core Products

Source: PHIP, CMBIS

Notes: 1. Early stage development denotes the process of data collection, data labelling and model training; 2. Late stage development denotes the process of data supplementation, algorithm training iteration and algorithm validation; 3. No regulatory approval or registration is required for the sale of Airdoc’s health risk assessment solutions in consumer healthcare environments; 4. Airdoc offers health risk assessment solutions with the ability to detect risk indicators, including risk assessments of retinal abnormalities, retinal vascular, vitreous abnormalities, retinal tumors, optic nerve pathologies, macular diseases, congenital anomalies of the retina, cardiovascular disease and anemia; 5. Early stage development denotes the process of product planning, product definition, engineering verification and design verification; 6. Pilot production denotes the process of production verification.

Market leader in providing integrated AI-empowered retina-based solutions

Airdoc is one of the first to provide AI-empowered retina-based early detection, diagnosis and health risk assessment solutions in China, according to F&S. Leveraging retinal imaging, multimodal data analyses and AI deep learning algorithms, the Company’s solutions differ from traditional chronic disease early detection and diagnosis, enabling non-invasive, accurate, fast, effective and scalable detection and diagnosis for whole population in both medical institutions and consumer healthcare providers. Airdoc-AIFUNDUS (1.0), an AI-based SaMD approved for auxiliary diagnosis of diabetic retinopathy, was the first of its kind to obtain the Class III medical device certificate from the NMPA

and the second AI-based retinal imaging analysis SaMD approved worldwide. In addition, Airdoc has developed a pipeline of other SaMDs and health risk assessment solutions to serve a wide range of customers in various healthcare environments, including community clinics, health checkup centers, insurance company, optometry centers and pharmacies. The comprehensive pipeline allowed the Company to offer its solutions in medical environments, as well as widely available consumer healthcare environments, further enforcing Airdoc's leading position in the market.

AI technology has disrupted many industries with its speed and cost-efficiency, accuracy and scalability advantages, fundamentally changing the traditional business model of many industries. Driven by the imbalanced allocation of medical resources, shortage of experienced physicians, technology upgrades and innovation, increasing government expenditure and policy support for AI-based medical imaging and growing capital support, China's AI-based medical imaging industry is on the cusp of explosive growth and is expected to grow from RMB0.3bn in 2020 to RMB92.3bn in 2030E at a 76.7% CAGR from 2020 to 2030E, according to F&S. With the NMPA approval of the Airdoc-AIFUNDUS (1.0) in August 2020, the Company believes that it has one of the most advanced platforms in this field with full capabilities from research and development, manufacturing, registration to commercialization, which enables the Company to rapidly advance innovative AI-based medical devices from concept to the market.

Airdoc's market leadership and first mover advantage has established high entry barriers. With its capabilities to offer software and hardware integrated solutions, advanced in-house developed AI algorithms, a comprehensive database of labeled real-world user retinal images, strong R&D team and KOL collaborations, as well as its multi-channel commercialization strategies and regulatory know-how, Airdoc is well-positioned to capture market opportunities and strengthen the Company's leadership position.

Airdoc-AIFUNDUS (1.0) is clinically validated with a high performance, demonstrating significant market potential

The Company's NMPA-approved AI-based SaMD, Airdoc-AIFUNDUS (1.0), is the first AI-empowered retina-based auxiliary diagnosis product to obtain the Class III medical device certificate from the NMPA. Approved in August 2020, Airdoc-AIFUNDUS (1.0) is used to assist in the diagnosis of diabetic retinopathy.

Among the AI-based medical imaging methods, AI-based retina diagnosis technology is clinically validated, supported by proof-of-concept clinical trial results of an FDA-approved, MOA-equivalent product and numerous peer-reviewed papers. In 2020, the Guidelines for the Prevention and Treatment of Type II Diabetes Mellitus in China (2020 Edition) (《中国2型糖尿病防治指南(2020版)》) also enlisted AI-based diabetic retinopathy screening software as an effective solution to assist in the diagnosis of diabetic retinopathy and recommended using NMPA-approved AI-based medical devices for early detection and diagnosis.

The Company developed Airdoc-AIFUNDUS (1.0) based on its AI-empowered retina-based early detection, diagnosis and health risk assessment technology platform, which has not only demonstrated industry-leading performance, but also broad applications in the diagnosis of a wide range of chronic diseases. AI-based retina diagnosis has significant health economic value. Diabetes is a major chronic illness in China with an estimated prevalence rate of 11.2% with a low diagnosis rate of only 43.3% and a low treatment rate of only 32.2%. Even with a low diagnosis rate, there were approximately 124.3mn people with diabetes in 2020, up from 115.9mn in 2015, according to F&S. Diabetic retinopathy is the most common complication for patients with diabetes. Early stage diabetic retinopathy is often asymptomatic. Regular and continuous monitoring of diabetic retinopathy could facilitate the evaluation of the progress of diabetes and therefore alleviate the risks of severe

complications such as diabetic nephropathy and diabetic cardiomyopathy. Up to 30% diabetes patients, or 37.3mn people, have diabetic retinopathy in 2020 in China. Because early stage diabetic retinopathy is often asymptomatic, approximately 90% diabetic retinopathy cases, or 33.6mn people, remain undiagnosed with a screening rate of less than 10% in China in 2020. Given the limited medical resources available and the imbalance of its allocation in China, there are needs for high performance and cost-effective medical devices to detect diabetic retinopathy, which would also signal risk of other complications associated with diabetes.

Designed to address such large unmet medical needs, Airdoc-AIFUNDUS (1.0) integrates advanced technologies in biomedical image processing, such as biomedical image quality evaluation, and sophisticated AI algorithms, such as deep learning algorithms, to process and analyze retinal images, providing early detection and diagnosis for chronic diseases that assist physicians to more efficiently and accurately diagnose patients. In its multi-center clinical trial with 1,000 enrolled patients, Airdoc-AIFUNDUS (1.0) demonstrated an industry-leading sensitivity of 91.75% and specificity of 93.1%. Moreover, Airdoc-AIFUNDUS (1.0) is widely compatible with most fundus cameras on the market, which enable the Company to be well-positioned to capture the significant market opportunity.

Comprehensive AI-based portfolio potentially addressing significant unmet market needs

The retina is the only part of the human body where blood vessels and nerve cells can be directly viewed in a non-invasive manner. Through retinal imaging, retinopathy and changes of retina can be directly observed and analyzed to detect, diagnose and assess risks of chronic diseases. Retinal imaging is the standard tool for identifying ocular diseases, such as diabetic retinopathy, pathological myopia, retinal vein occlusion, glaucoma and AMD. It also plays an important role in detecting and diagnosing other chronic diseases, including hypertension, diabetes, ICVD, Parkinson's disease and anemia. Many of these chronic diseases have significant patient populations in China, with 324.4mn with hypertension and approximately 151.5mn with cataracts in China in 2020, according to F&S. Leveraging Airdoc's innovative AI-based algorithms and vast real-world database, the Company has developed and are strategically developing other SaMDs for glaucoma, cataracts, ICVD and ASCVD, gestational diabetic retinopathy, gestational hypertensive retinopathy, papilledema intracranial hypertension retinopathy and anemia.

In addition to addressing the growing demand for chronic disease early detection and diagnosis, the Company has developed health risk assessment solutions capable of detecting risk indicators associated with a wide range of diseases and lesions. Airdoc's health risk assessment solutions have been marketed to a wide range of customers in various healthcare environments to efficiently conduct health risk assessment for a large population. Airdoc is developing new indications for health risk assessment solutions, including hyperthyroidism, graves ophthalmopathy, retinal vein occlusion, dementia, Parkinson's disease, atrial fibrillation and arteriosclerosis.

Integrated solutions combining in-house developed AI-based software and hardware

Airdoc is one of the few in the industry that has in-house developed image analysis technology as well as image capture technology, which enables the Company to offer highly integrated and end-to-end optimized solutions that combine software and hardware with better user experience and higher accuracy. The Company has three in-house developed proprietary and fully automated fundus cameras that are easy to use and easy to manage. The Company's hardware devices significantly lower the barriers for physicians to offer eye screening and are applicable in multiple medical and consumer healthcare environments. The hardware devices are powered by on-device AI technologies such as speech recognition, speech synthesis and computer vision and can successfully address pain points of existing fundus cameras on the market at a fraction of the cost, making its products more affordable to various healthcare environments, therefore facilitating the sales of AI-based solutions.

By offering software and hardware as a bundle, Airdoc believes its integrated healthcare solutions provide an improved user experience, seamless end-to-end performance and a cost-effective option that make it the solution-of-choice to customers. Its integrated solutions also enable Airdoc to optimize its portfolio from data collection, data transmission, data analysis and result reporting to realize its full potential. For example, the Company is able to control many imaging parameters in the hardware to ensure that the image is ideal to be processed and analyzed by its AI deep learning algorithms.

In March 2021, Airdoc completed the registration of its AI-FUNDUSCAMERA-P, a portable, fully automatic and fully self-service fundus camera, as a Class II medical device in China and had commenced commercialization since then. Airdoc's AI-FUNDUSCAMERA-D, which is currently at research and development stage, is a desktop fundus camera with comparable image quality but significantly lower costs than traditional high-end desktop fundus cameras. The Company expects to apply for a Class II medical device registration certificate for its AI-FUNDUSCAMERA-D in the second quarter of 2022E. Its AI-FUNDUSCAMERA-M is a multimodal health scanner in the research and development stage. Airdoc expects to apply for a Class II medical device registration certificate for its AI-FUNDUSCAMERA-M in the fourth quarter of 2023E.

Strong research and development capabilities

Airdoc focuses on developing AI-empowered and retina-based technology to enhance its existing pipeline and to provide comprehensive and multi-faceted high-quality AI-based solutions for chronic disease early detection and diagnosis. The Company has primarily focused on developing deep learning algorithms, processing and labeling medical data, developing engineering infrastructures for algorithm training and data analysis, and developing technologies for its hardware devices.

Airdoc is one of the few in the industry that offer solutions that integrate hardware, software, algorithms and services together as one product. While its AI-based SaMDs are compatible with various fundus cameras on the market, Airdoc believes that its in-house developed hardware devices powered by on-device AI technologies provide an improved user experience, better algorithm optimization with its software, seamless end-to-end performance and cost-effectiveness that make it the solution-of-choice to customers.

Strong and experienced R&D team

Airdoc incurred research and development expenses of RMB41.2mn, RMB42.3mn, RMB11.0mn in 2019 and 2020 and the three months ended March 31, 2021, respectively. As of June 13, 2021, Airdoc's R&D team consisted of over 60 members, all of whom hold bachelor's or higher degrees. Its R&D team has deep experience in AI technologies and medicine with a full spectrum of expertise across deep learning, medicine, computer vision, data analytics, Internet service, medical devices, biology and other disciplines.

Airdoc's founder, Mr. Zhang, has accumulated nearly 12 years of experience in R&D of AI technology and know-how and management of high-tech companies. Previously, he served as a program manager of Microsoft (China) Co., Ltd. (微软(中国)有限公司), the chief technology officer of Ethos Technologies Inc. (宇思信德科技(北京)有限公司), a vice president at Synapse Computer System (Shanghai) Co, Ltd. (突触计算机系统(上海)有限公司) and a product vice president of Sina Technology (China) Company Limited (新浪网技术(中国)有限公司).

Dr. He Chao, the Company's chief technology officer, brings approximately 20 years of software development, algorithm design and hardware development experience and owns over 30 US or EU patents or patent applications in these areas. He has led the development of Airdoc's deep learning algorithms, which laid the foundation for the development of Airdoc-AIFUNDUS.

Dr. Chen Yuzhong, Airdoc's chief medical officer, has approximately 20 years of frontline experience applying technology to clinical practice, including in Grade IIIA hospitals.

Airdoc's in-house R&D team is further divided into the following functional departments: (i) business application department, which is responsible for the development of detection, diagnosis and health risk assessment solutions; (ii) algorithm and data department, which is responsible for the development of algorithms and data platform; (iii) hardware department, which is responsible for the development of industrial design, mechanical structure, optical design, firmware system, algorithms and application of its hardware devices; (iv) efficiency and quality management department, which is responsible for test and quality, data and feedback collection, process and efficiency, security and compliance; (v) product registration team, which is responsible for product registration related work such as registration test, clinical trial and registration application; and (vi) medical research team, which is responsible for researching new applications of AI technology in medical field.

Top industry awards proved Airdoc' strong innovation capability

Airdoc's innovative Airdoc-AIFUNDUS (1.0) is a testament to its strong research and development capabilities. Due to its innovative nature, Airdoc-AIFUNDUS (1.0) was approved by the NMPA through a fast-tracked regulatory approval process and was the first NMPA-approved AI-based SaMD used to assist in the diagnosis of diabetic retinopathy. The Company received the Wu Wen Jun AI Science & Technology Progress Award (吴文俊人工智能科技进步奖) in 2019, which is widely recognized as the highest award for intelligent science and technology and the highest honor in the field of AI in China. In 2017, Airdoc was the only AI medical company featured at the Microsoft Build Developer Conference, one of the world's top conference events to present major technology milestones in software engineering, for its Airdoc-AIFUNDUS (1.0). Airdoc has partnered with renowned academic research institutions on a key national research and development project to develop digital diagnosis equipment. It has over 20 papers published on prestigious peer-reviewed scientific journals, including the Lancet series, British Journal of Ophthalmology, British Journal of Dermatology, and presented at influential academic conferences in AI, such as MICCAI. Moreover, the outstanding performance of Airdoc's products have been featured in various prestigious peer-reviewed scientific journals, including the Nature series.

Extensive network with top hospitals and KOLs

Airdoc maintains solid relationships with top hospitals nationwide, such as Zhongshan Ophthalmic Center of Sun Yat-Sen University (中山大学中山眼科中心), Beijing Tongren Hospital affiliated with the Capital Medical University (首都医科大学附属北京同仁医院), the First Medical Center of China PLA General Hospital (解放军总医院第一医学中心), Shanghai General Hospital (上海交通大学附属第一人民医院), Beijing Anzhen Hospital affiliated with the Capital Medical University (首都医科大学附属北京安贞医院), Beijing Tsinghua Changgung Hospital affiliated with the Tsinghua University (清华大学附属北京清华长庚医院), Eye Hospital of Wenzhou Medical University (温州医科大学附属眼视光医院) and, influential academic institutions, such as Peking University and Monash University, and influential KOLs, to better understand the needs of frontline clinical care and enhance its R&D capabilities. Airdoc's network of KOLs has been a valuable resource for product development feedback and crucial to its product gaining acceptance and recognition in medical institutions.

Stringent R&D process of Airdoc

Airdoc has established and strictly followed an internal protocol that governs the design, development and test of its algorithms, software and hardware. Its R&D team is in charge of its entire research and development process. To ensure compliance and highly efficient registration and commercialization,

employees from different departments, covering registration, medical and sales teams, are also deeply involved in the research and development process.

Figure 3: Design and development process of Airdoc's algorithms and software



Source: PHIP, CMBIS

(1) Product proposal application and review. The product team prepares a project proposal report, collects and analyzes the customers' needs. The heads of sales, operations and medical departments are required to attend the product proposal meeting and provide their opinion in terms of market needs, operational feasibility, medical science and clinical value.

(2) Product design and development. The product team designs the product candidate in terms of function, performance, usability and safety requirements, at the same time lists the development and delivery timeline. Data labelling is an important step of the Company's algorithms design and development, which serves as the foundation for the continued training and optimization of its deep learning algorithms. The R&D team will set the scope, tools, methods and procedures used in data labelling, and the Company will then engage external medical experts to cross-label the data. Deep learning algorithm design is another important task. Airdoc will analyze the problem and design a deep learning algorithm for it. The design of deep learning algorithm includes division of data into training, verification and test subsets, design of data augmentation, design of neural network's architecture and selection of hyper-parameters for training. After deep learning algorithm design the next step is deep learning algorithm training. In training, massive amount of labeled data is fed into the deep learning algorithm to help algorithm learn from the data and converge to a deep learning model which will be used to analyze input images and make decision or prediction for the image. Responsible personnel at every stage of the project design and development should review and analyze the design of the project candidate to ensure its feasibility. After completing the review, Airdoc's research and development team will develop the product candidate according to the design plan. Otherwise, the design shall be revised and reviewed again.

(3) Delivery and validation of design and development. The product candidate will be delivered to a testing team, which will conduct tests on the product candidate's functions and overall performance. Airdoc will conduct an internal review of the product candidate in terms of research and development, sales, marketing, customer services, medical and legal departments. The Company may also invite third-party experts to conduct an external review, which enables it to continue to optimize the product candidate, and ensures its compliance with the prescribed application and clinical evaluation.

(4) Verification and registration of the product. Airdoc will initiate clinical trials and various registration-related work streams if required before the launch of its product.

Airdoc's state-of-the-art technology platforms

Airdoc's AI-empowered retina-based early detection, diagnosis and health risk assessment solutions are driven by (i) AI deep learning algorithms, (ii) comprehensive and high-quality database and (iii)

highly efficient and mature AI engineering infrastructure.

To optimize its AI deep learning algorithms, Airdoc has developed a broad range of algorithms for disease classification, lesion detection, lesion segmentation and health risk assessment, which work together to deliver highly accurate analysis results. Airdoc has developed over 50 AI deep learning algorithms serving real-world customers. The Company has developed a robust IP portfolio covering key technologies for its software, hardware devices and algorithms, with 134 patents and patent applications in China and six published PCT applications.

Airdoc has developed one of the largest databases of retinal images in the world through research collaboration and serving a wide range of customers across China. Its data diversity is leading in the industry, comprehensively covering ages, genders, demographics, diseases, commercial channels and medical device models. Its database includes approximately 3.7mn real-world user retinal images with their corresponding multimodal data, cross-labeled by hundreds of medical experts, enabling the Company to perform more in-depth medical AI research and development and to build and enhance its AI deep learning algorithms. Its extensive database has served as a key entry barrier for competitors, given the extensive associated costs and the increasingly stringent data protection standards.

Airdoc has established a highly secure and efficient private data lake system to store large and varied data sets, a big data analytic system to gain insight into the data and a data syncing system to reliably and efficiently sync data from different sources to the data lake system.

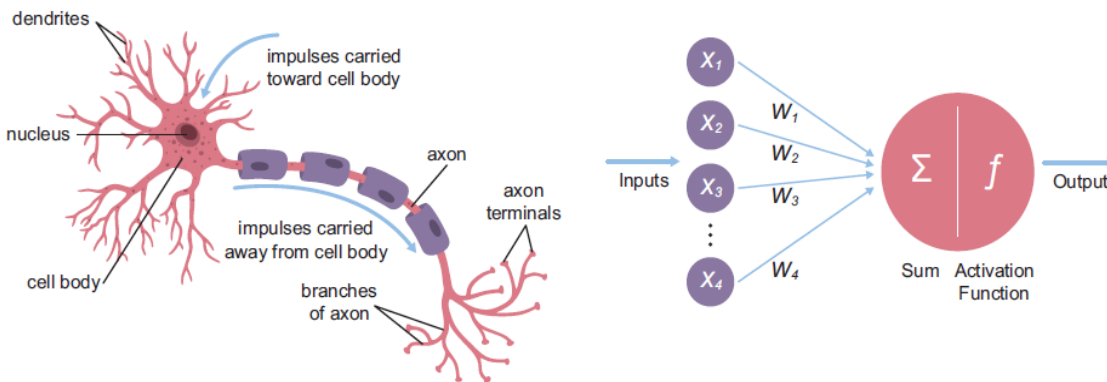
The Company also has a powerful AI algorithm training system, which uses deep learning training frameworks to develop deep learning algorithms and train deep learning models using a massive amount of data. The deep learning model is built upon what deep learning algorithms have learned from the data. The deep learning models are later used in Airdoc's online inference system to analyze medical images. Its training system was built to support five different machine learning frameworks and six programming languages to facilitate the development of its AI algorithms and address various pain points in algorithm optimization. Due to the complexity of analyzing a wide range of diseases and lesions, Airdoc has also developed a highly efficient and comprehensive online deep learning inference system to support synchronistic computing across over 300 deep learning model instances, optimize the use of data and computation resources and streamline its deep learning model optimization, protection, deployment, management and monitoring.

Airdoc's Deep learning algorithms

Deep learning is a type of algorithms developed to perform intelligent tasks, in Airdoc's case, the early detection and diagnosis of chronic diseases, by mimicking the neuronal connectivity of the human brain. Humans rely on their nervous system to learn from experience, perceive their surroundings, and react appropriately. The nervous system consists of interconnected neurons among other supporting cells. Neurons are the basic unit of the nervous system and generate electrical signals called action potentials, which allow them to quickly transmit information throughout the brain. When a neuron receives incoming signal, it processes it to determine whether or not to pass it along. The human brain consists of 60 to 80 billion neurons, which work together to process complex sensory input to generate intelligent responses.

Carefully developed schemes of connectivity and computation enable these artificial neural networks to learn to carry out highly complex computations, such as the generation of highly accurate detection and examination results from retinal image inputs. In a nutshell, deep learning's artificial neural network is a very complex computation network or equation which processes input data such as images, generates a computational result, and the result can be used as a classification decision, including whether the image shows a certain chronic disease such as diabetic retinopathy.

Figure 4: Biological neuron versus artificial neural network

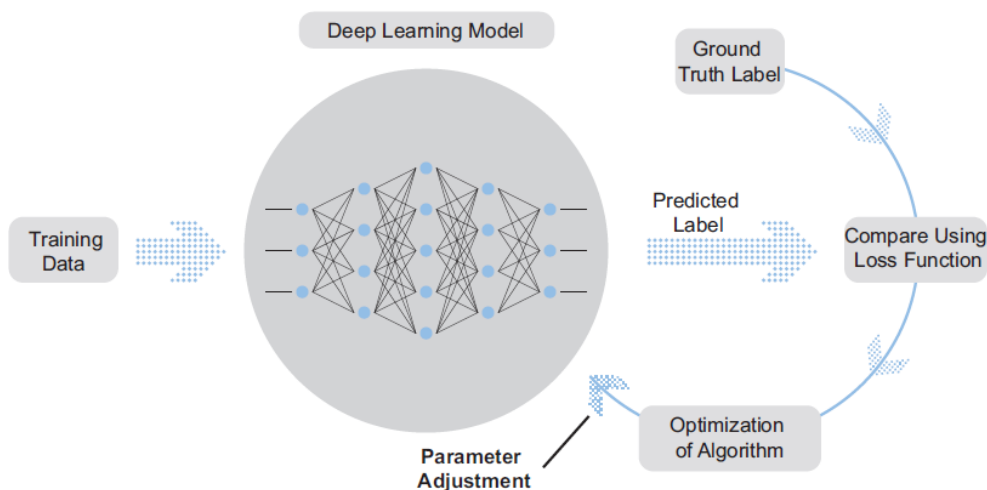


Source: PHIP, CMBIS

The development of deep learning algorithms involves two major phases: design and training. Design is to build the architecture of the computation network, including the number of layers, number of nodes in the layers and connectivity among nodes. However, designing the architecture does not determine the internal parameters of the computation network, such as how much the algorithm amplifies, suppresses or mixes a signal in the network. Training is where Airdoc decides the values of those parameters by learning from human-labeled training data.

In training, training data such as retinal images are first labeled as different classes, such as being healthy or having diabetic retinopathy, by human experts as ground truth labels. Next, the computation network runs a forward pass through the data, predicting labels for the training data. Such predictions are then compared against the ground-truth labels in the data, and an error signal is generated through a loss function. This error is then propagated back through the network, and parameters are adjusted using a chosen optimization algorithm in order to reduce the same error in the future. This training process must be repeated many times until a good or good enough set of parameters is discovered. After training, the parameters are fixed and the computation network with fixed parameter values becomes the final deep learning model, which would be used in deep learning inference.

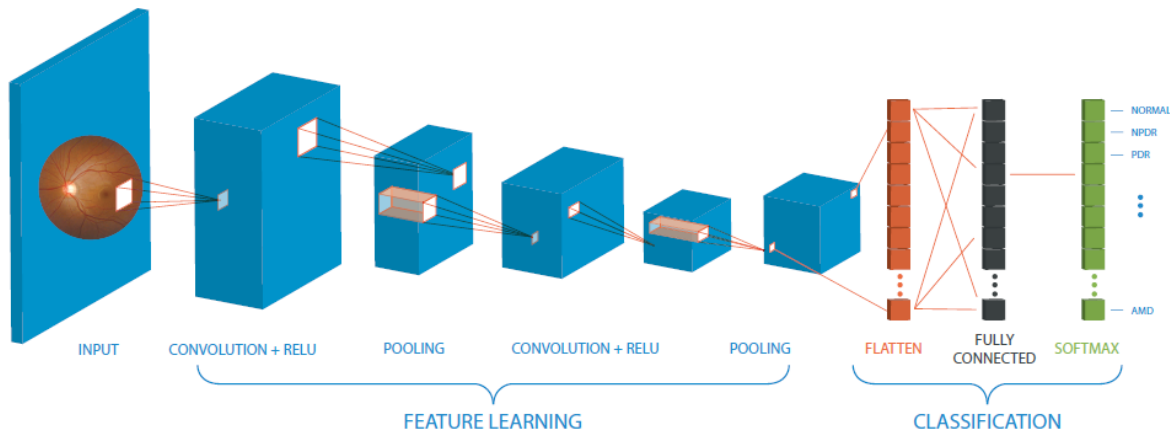
Figure 5: Airdoc’s deep learning model



Source: PHIP, CMBIS

Deep learning inference is where a trained deep learning model is used to process input data such as retinal image, compute via the computation network, and make a prediction and decision such as whether the input image shows diabetic retinopathy. Unlike training, the inference stage does not include back-propagation and parameter-tuning. In this stage, the deep learning model is deployed to make predictions or decisions on real-world data. The trained deep learning model will deduce a conclusion from the input data using the computation network.

Figure 6: Inference of Airdoc's deep learning model



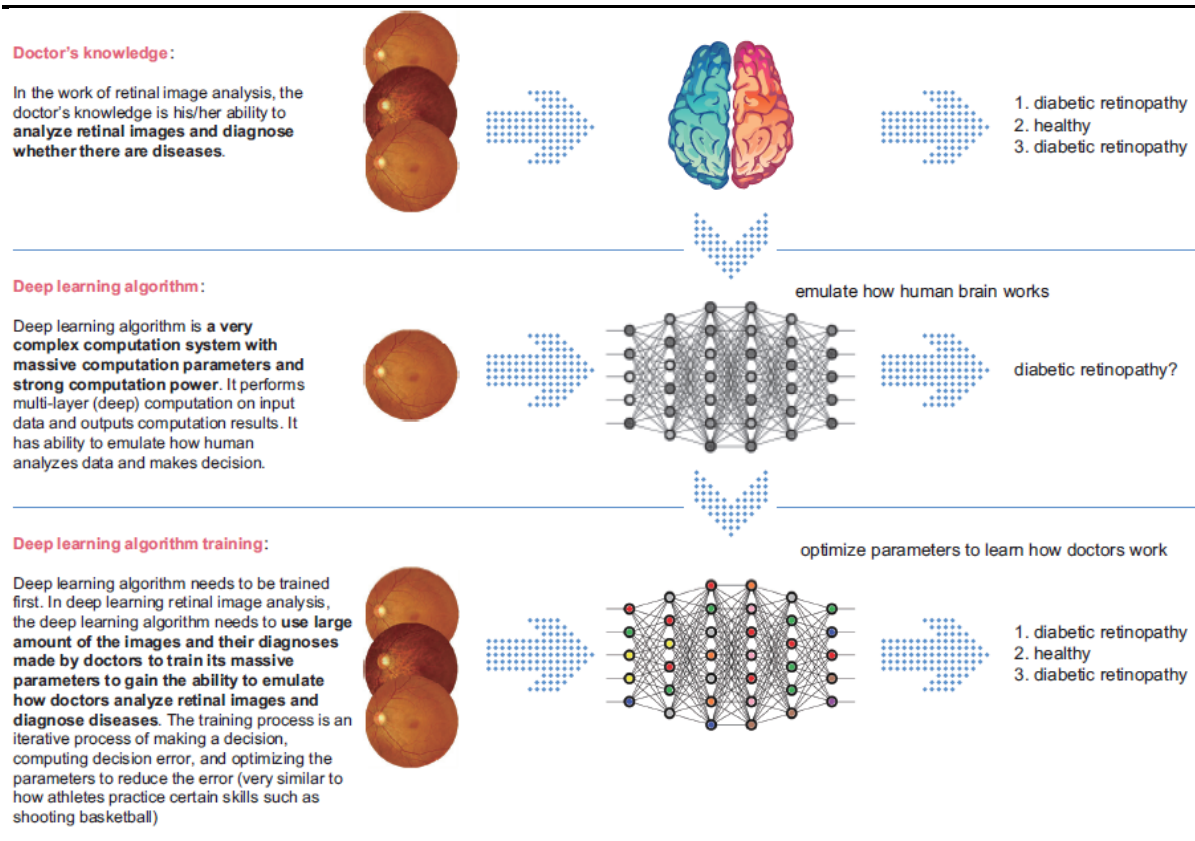
Source: PHIP, CMBIS

Applications of deep learning in retinal image analysis include disease classification, lesion detection, lesion segmentation and health risk assessment. Considering the complexity of the problems, Airdoc has developed over 50 deep learning algorithms to cover a comprehensive range of diseases, lesions and health risks. The training process involves feeding algorithms the retinal images labeled by medical experts, computing the predicted result using Airdoc's computation network, comparing the predicted results with human labels and adjusting the parameters to minimize prediction errors. After being exposed to numerous labeled retinal images, the algorithm generalizes and learns to predict certain chronic diseases accurately using a computation network which represents the mathematical relationships between input data and predicted results.

Airdoc's database

The database serves as the foundation for its deep training algorithms to accurately pinpoint conditions related to chronic diseases. Large and rich sets of data are required for the training, validating and testing of deep learning algorithms. Airdoc has developed one of the largest retinal image databases in the world through research and commercial collaboration. In training its deep learning models to accurately pinpoint disease-related conditions, its database enables the continued optimization of its existing algorithms and the continued development of new algorithms that target new indications. Airdoc's data diversity is leading in the industry, comprehensively covering ages, genders, demographics, commercial channels, medical device models and diseases. The Company has also developed data sets for different healthcare environments, such as early detection, diagnosis and health risk assessment, to meet the needs of its customers. Its database includes approximately 3.7mn real-world user retinal images with their corresponding multimodal data and cross-labeled by hundreds of medical experts, enabling Airdoc to perform more in-depth medical AI research and development and to build and enhance its deep learning algorithms.

Figure 7: Demonstration of AI deep learning model



Source: PHIP, CMBIS

Airdoc's engineering infrastructure

Airdoc's engineering infrastructure is the building block on which its deep learning algorithms are developed, tested, evaluated and deployed. It supports every stage of deep learning workflows by enabling developers and engineers to manage data resources, develop deep learning algorithms and deploy deep learning models. The engineering infrastructure supports algorithm design, algorithm training, data labeling, data management, data ingestion, model testing and verification, model deployment, model inference, and service monitoring.

Airdoc's deep learning algorithm training system uses deep learning training frameworks to train and optimize algorithms to analyze medical images, addressing various pain points in algorithm optimization. Due to the complexity of analyzing various chronic diseases and lesions, its training system was built to support six programming languages and be compatible with five different machine learning frameworks.

Airdoc has established a highly secure and efficient private data lake system, a big data analysis system and a data syncing system, which are critical to its ability to manage and analyze real-world data to rapidly train and optimize deep learning algorithms in near real time.

Airdoc also developed a highly efficient and comprehensive deep learning inference platform to streamline its deep learning model optimization, protection, deployment, management and monitoring, to process retinal image inputs from users, and support synchronistic computing across over 50 deep learning models and 300 deep learning model instances.

Multi-channel commercialization strategy with a solid and diverse customer base to maximize market potential

Airdoc is one of the first to commercialize AI-empowered retina-based early detection, diagnosis and health risk assessment solutions in China, according to F&S. Benefitting from a multi-channel commercialization strategy, it has rapidly penetrated the market and has developed a solid and diverse customer base to maximize the market potential of its AI-empowered retina-based early detection, diagnosis and health risk assessment solutions in China. As of June 13, 2021, its solutions have been used in a variety of healthcare environments, including clinical departments in hospitals, community clinics, health checkup centers, insurance companies, optometry centers and pharmacies. With these customers in mind, Airdoc has developed and optimized algorithms to address their needs and accommodate the unique features of their business with the support of its comprehensive database.

Airdoc had established a sales network, covering 27 provinces in China as of June 13, 2021. Airdoc primarily offered its customers integrated solutions of software and hardware. The Company may from time to time provide its SaMDs to customers who already have compatible hardware devices and charge them separately, to promote its penetration in market.

As of June 13, 2021, the Company had established an in-house sales and marketing team of 85 members to provide its customers with customized supports. Airdoc's sales and marketing team is divided into various functions covering different geographic regions and different channels. The Company provides sales and marketing personnel with comprehensive training covering its corporate culture, product pipeline, medical theories, collaboration resources, sale procedures, price system and marketing system. In 2019 and 2020 and the three months ended March 31, 2021, Airdoc generated direct sales revenue of RMB27.8mn, RMB45.8mn and RMB21.0mn, respectively, representing 91.5%, 96.1% and 94.7% of its total revenue. During the same periods, Airdoc also generated a small amount of revenue of RMB2.6mn, RMB1.9mn and RMB1.2mn, respectively, through distributors, representing 8.5%, 3.9% and 5.3% of the Company's total revenue.

Sales channel in medical institutions

Airdoc has focused on the coverage of key clinical departments in hospitals, community clinics and health checkup centers, aiming to address the shortage of medical resources and imbalance of its allocation in China.

(1) Clinical departments in hospitals. The demand for health services in China has far outstripped supply. Traditionally, chronic diseases and their associated complications are detected and diagnosed manually by physicians after reviewing various test results, such as retinal images. However, there is a limited number of experienced physicians in China. According to F&S, there were only approximately 44,800 ophthalmologists in China as of December 31, 2020, facing with increased patient volume. Airdoc believes its AI-based early detection and diagnosis solutions could address significant unmet needs for affordable and effective solutions for chronic diseases by enhancing diagnosis capabilities, improving treatment compliance, and offering non-invasive, accurate, fast, highly-effective and scalable diagnosis solutions. Since obtaining NMPA approval for Airdoc-AIFUNDUS (1.0), the Company has focused on increasing its brand reputation and awareness among KOLs and physicians, which Airdoc believes will enable it to rapidly expand its penetration in hospitals.

(2) Community clinics. Medical resources, including experienced physicians and advanced medical equipment, are unevenly concentrated in a small number of major hospitals in China, while many regional hospitals cannot meet the needs of the large population living in these areas. Although the PRC government has established a series of policies to support the development of community clinics, China still faces problems of controlling costs, increasing access and providing quality healthcare at

community clinics. With Airdoc's AI-based early detection diagnosis solutions, community clinics can more accurately and cost-effectively detect and diagnose chronic diseases and offer referral advice for a large population, effectively addressing the shortage and uneven distribution of medical resources in China.

(3) Health checkup centers. Health checkup centers offer routine checkups to detect potential diseases and/or medical conditions. However, many health checkup centers need to conduct a large number of tests for comprehensive screening. Airdoc's AI-empowered retina-based early detection, diagnosis and health risk assessment solutions address the needs of health checkup centers for comprehensive, accurate, fast and highly-effective health checkup products that cover multiple diseases and lesions. Its solutions enable early detection, diagnosis and health risk assessment with only one quick shot of retina, which is relatively low-cost and non-invasive, enabling health checkup centers to provide high-quality services and increase testing capacity. Airdoc began to work with iKang, a leading health checkup center chain in China since 2018. As of June 13, 2021, the Company had implemented its AI-based solutions in over 140 iKang health checkup centers. Airdoc is also actively expanding its coverage to over 10,000 health checkup branches, including public hospital health checkup departments. Airdoc plans to gradually expand its coverage to health checkup departments in public hospitals, which play an important role in the PRC health checkup industry.

Sales channel in consumer healthcare environments

(1) Insurance companies. Airdoc has partnered with leading commercial insurance companies such as Ping An Insurance (平安保險), China Pacific Insurance (中國太平洋保險), China Life Insurance (中國人壽), Taiping Life Insurance (太平人壽保險) and New China Insurance (新华保險) to assist them in comprehensively evaluating the health conditions of insurance applicants and insured members accurately and efficiently. As chronic disease prevalence rises, insurance companies have a growing need to identify chronic disease risk factors to better understand their customers' health conditions, provide health management advice, offer customized insurance products and provide adequate protection. As of June 13, 2021, Airdoc has provided health risk assessment solutions to branches of insurance companies in 28 provinces and expect to further expand its coverage as it ramps up sales of its hardware devices and penetrate more branches.

(2) Optometry centers. Optometry centers in China are gradually enhancing their service capabilities to offer value-added services, such as health risk assessment, to consumers and therefore have significant needs for risk assessment for vision related disease solutions to support their growing new business line. Airdoc provides its health risk assessment solutions to Nova Vision, a leading optometry chain in China, to provide a comprehensive analysis of customers' retinal environment and identify risk factors that may lead to impaired vision, which help optometry centers raise awareness for eye health, especially in younger populations. As of June 13, 2021, Airdoc's health risk assessment solutions covered over 740 optometry centers and over one million consumers and are expected to cover 1,200 stores in 2021E.

(3) Pharmacies. As of December 31, 2020, there were over 554,000 retail pharmacies in China, according to F&S. Airdoc believes retail pharmacies in China will gradually play an important role in providing accessible and affordable healthcare as health management and telemedicine services increase, becoming the landing point for various healthcare services in the healthcare ecosystem. As such, pharmacies will have a growing need for AI-based health risk assessment solutions to support their operations. Airdoc has worked with Gaoji Health (高济医疗), a leading retail pharmacy, to provide continuous health management solutions and enhance its competitiveness and service capabilities.

Through its multi-channel commercialization strategy, Airdoc has built up a diverse customer base and increased its geographical presence. From 2019 to 2020, the number of its customers increased from

46 to 85. Its ability to serve a wide customer base has also enriched its real-world user database, creating a feedback loop to further optimize its deep learning algorithms.

Marketing Strategy

Airdoc adopts an academic marketing approach to introduce its solutions to the market. The Company's marketing efforts are facilitated through both online platforms and offline channels to its existing customers and potential new customers. Airdoc's academic marketing and promotion activities primarily include participating in medical conferences and industry exhibitions. For example, to improve the awareness and clinical knowledge of physicians, the Company has participated in academic conferences, such as MICCAI and "301 Health Forum". In addition, Airdoc is exploring opportunities to collaborate with governments with respect to government-sponsored healthcare projects. The Company released the "First Retinal-AI Based Blue Paper on the Health of One Million Chinese Medical Examination Population (第一个基于视网膜人工智能评估的《百万体检人群健康蓝皮书》)" together with iKang and National Science and Technology Information Resources Comprehensive Utilization and Public Service Center Ophthalmology Big Data Joint Laboratory in 2020. In addition, Airdoc plans to participate in government sponsored activities, such as the "Healthy China Action Plan (健康中国)" promoted by the National Health Commission of the PRC, to increase the awareness of the chronic disease early detection and management.

Airdoc also promotes the awareness of its solutions through (i) providing training to customers; (ii) partnership with hospitals and research institutions; and (iii) participating in the revision and update of the relevant industry standards. To increase awareness of its AI-empowered retina-based early detection, diagnosis and health risk assessment solutions, the Company provides training to the customers regarding the use of its solutions through regular visits and communications, on-site demonstration and other activities. As Airdoc provides innovative solutions for the early detection and diagnosis of chronic diseases, physicians or other operators becoming more knowledgeable and experienced with the Company's solutions will help Airdoc gain higher acceptance and adoption. Particularly, to help physicians to use its solutions smoothly and accurately, Airdoc provides various trainings to physicians, including (i) trainings in relation to the operations of its SaMDs and hardware devices, (ii) trainings in relation to medical background and clinical procedures for using its SaMDs, and (iii) trainings in relation the mechanism and other information of its SaMDs. Furthermore, Airdoc actively participates in the revision and update of the relevant industry standards. For example, the Company actively provided its comments and feedback on the Guiding Principles for the Classification and Definition of AI-based Medical Software Products (Draft for comments) (《人工智能类医用软件产品分类界定指导原则》征求意见稿) released by the NMPA in April 2021.

Airdoc plans to set up AI-empowered retina-based diagnosis workstations in influential hospitals to further promote the research and development of its joint projects and technology development of AI-empowered retina based early detection, diagnosis and health risk assessment solutions. The Company will provide its Airdoc-AIFUNDUS (1.0) to hospitals. With the increasing familiarity of the Company's products and technologies, Airdoc will hold academic conferences to enable its workstations serve as an effective platform for the Company to interact with medical practitioner to discuss pain points of the detection and diagnosis of chronic diseases, product innovation and solutions to medical needs. To date, Airdoc has set up nine workstations in leading hospitals in Beijing, as well as Jiangsu, Hubei, Guangdong and Jilin provinces.

SaMDs for detection and diagnosis

The retina is a multilayered structure that detects light, processes the subsequent signals, and transmits the processed information to the brain. It is the only part of the human body where blood vessels and nerve cells can be directly observed in a non-invasive manner. Retinal images can help physicians diagnose not only vision-threatening eye diseases, such as diabetic retinopathy, AMD and glaucoma, but also life-threatening chronic diseases such as stroke, cardiovascular disease and neurological disorders such as Alzheimer's disease.

Currently, the retina is observed manually by physicians using retinal images captured by fundus cameras. Diagnoses and detection conducted through manual observation rely heavily on physicians' training and experience, are relatively subjective and not standardized, and require physicians to spend extensive time in the review process.

Airdoc-AIFUNDUS, the core product

Airdoc-AIFUNDUS is an AI-based SaMD that uses sophisticated deep learning algorithms to accurately detect and diagnose chronic diseases from retinal images. The Company developed Airdoc-AIFUNDUS based on its proprietary AI-empowered retina-based early detection, diagnosis and health risk assessment technology platform, which is driven by deep learning technologies and fully validated in terms of scientific theory, clinical trial data and clinical pathway.

The Company has three versions of Airdoc-AIFUNDUS in its portfolio. Airdoc-AIFUNDUS (1.0), which obtained a Class III medical device certificate from the NMPA in August 2020, is indicated for the auxiliary diagnosis of diabetic retinopathy. Airdoc-AIFUNDUS (2.0) is designed for the auxiliary diagnosis of hypertensive retinopathy, retinal vein occlusion and AMD. Airdoc plans to commence its multi-center clinical trial for Airdoc-AIFUNDUS (2.0) in October 2021E and apply for a registration approval of new indications with the NMPA in the second quarter of 2022E. Airdoc-AIFUNDUS (3.0) is designed for the auxiliary diagnosis of pathological myopia and retinal detachment. Airdoc plans to commence multi-center clinical trial for Airdoc-AIFUNDUS (3.0) in October 2022E and apply for a registration approval of new indications with the NMPA in the first half of 2024E.

Airdoc-AIFUNDUS (1.0), (2.0) and (3.0) are (i) developed based on same technical methodologies, (ii) the same with respect to the main structure or composition; and (iii) used for diagnose and detection of certain chronic diseases by way of retinopathy detection.

The Company has consulted with the relevant branch of the NMPA, which has confirmed that (i) Airdoc-AIFUNDUS (1.0), Airdoc-AIFUNDUS (2.0) and Airdoc-AIFUNDUS (3.0) will be regulated as one product; (ii) Airdoc-AIFUNDUS (2.0) and Airdoc-AIFUNDUS (3.0) will be registered as the expansion of indications under the Class III registration certificate of Airdoc-AIFUNDUS (1.0), together with the modification documents issued by the NMPA; and (iii) Clinical trial for Airdoc-AIFUNDUS (2.0) is required by the NMPA for the purpose of seeking approval for the modification application.

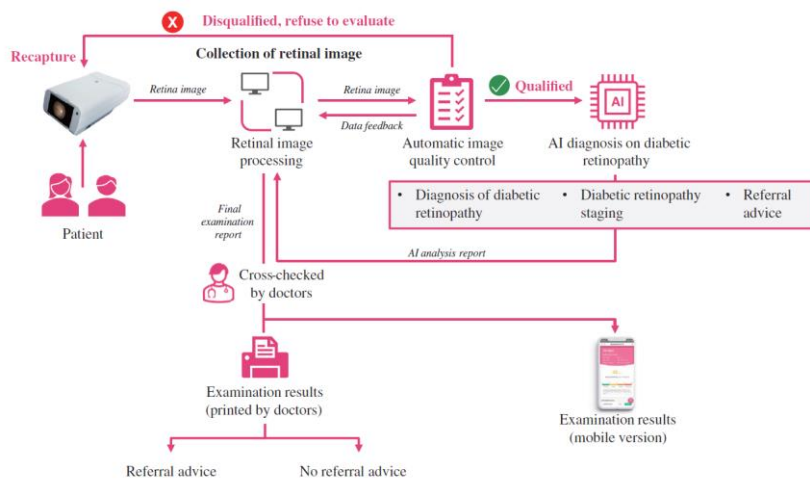
Considering Article 5 of the Announcement of the NMPA on Issuing the Special Review Procedures for Innovative Medical Devices 《(国家药品监督管理局关于发布创新医疗器械特别审查程序的公告)》 and other applicable PRC rules and regulations, the relevant provincial branch of the NMPA is responsible for interpreting NMPA rules, conducting a preliminary review on whether the medical device meets the requirements of innovative medical devices, and issuing preliminary review assessments to the NMPA. Airdoc's PRC Legal Advisors are of the view that (i) the relevant provincial branch of the NMPA is a competent authority to interpret the NMPA rules applicable to Company and has the authority to assess the procedures applicable to expansion of indications of Airdoc-AIFUNDUS and provide the above confirmations; and (ii) the NMPA will issue the registration certificate of Airdoc-

AIFUNDUS based on the assessment performed and submitted by the relevant provincial branch of the NMPA.

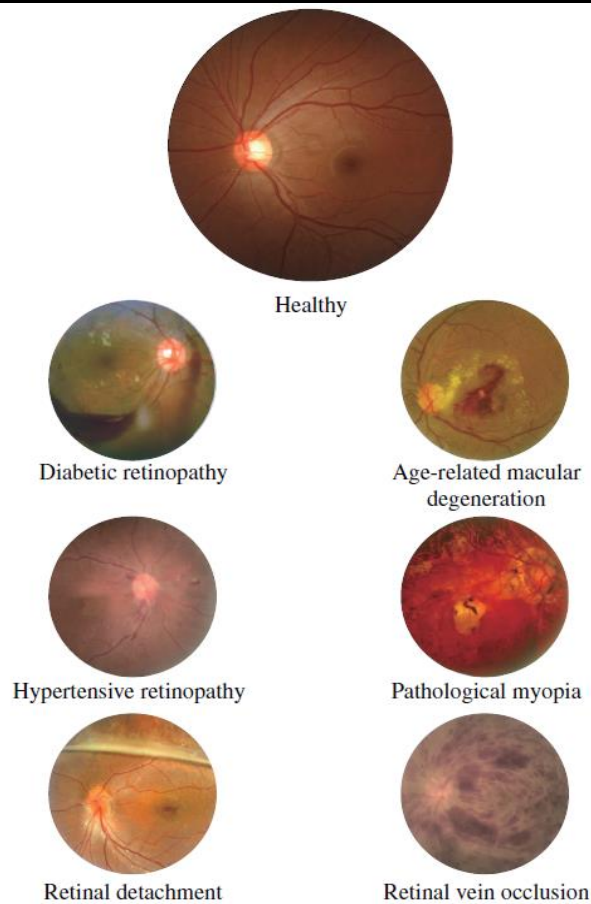
Workflow of Airdoc-AIFUNDUS

The workflow of Airdoc-AIFUNDUS involves three major steps: retinal image collection, image quality control and imaging analysis and classification. Retinal images are collected through a fundus camera connected to a computer, where Airdoc-AIFUNDUS is installed. At least one fundus image per eye will be taken. The operator then uses Airdoc-AIFUNDUS software to upload the images to Airdoc’s backend imaging analysis cloud platform, which will review the image quality, including the resolution, brightness, color, noise level and view angle to ensure high-quality retinal images are obtained. The cloud platform is supported by public cloud services provided by well-known cloud service providers. According to Airdoc’s agreements with the cloud service providers, they will provide cloud infrastructure and operational maintenance services such as the cloud server (i.e. elastic computing service, or ECS) and relational database services. Such cloud service providers adopt various measures to ensure compliance with the prevailing regulations. They also comply with a series of national or international standards in relation to cloud service security such as ISO/IEC 27001 and ISO/IEC 22301. The Company’s Airdoc-AIFUNDUS then uses deep learning algorithms to analyze the images and classify them by disease using complex computations that detect and analyze diseases and lesions including microaneurysms, hemorrhages, exudates and swelling or fatty deposits by texture, pattern and shape. Upon completion of the analysis, a report is generated with the retinal images, examination results, disease progress and referral advice. Airdoc’s solution will give referral advice for referable diseases, such as mild or more than mild non-proliferative diabetic retinopathy. Physicians can refer to the report when providing their diagnoses and medical advice. Physicians may also refer to the report to determine whether referral to other departments, such as the ophthalmology department, for follow-up consultations is necessary.

Figure 8: Workflow of Airdoc-AIFUNDUS



Source: PHIP, CMBIS

Figure 9: Demonstration of retinal images


Source: PHIP, CMBIS

Multiple advantages of Airdoc-AIFUNDUS

(1) First NMPA-approved Class III AI-empowered retina-based auxiliary diagnosis product in China. Airdoc-AIFUNDUS (1.0) is the first of its kind to be used to assist in the diagnosis of diabetic retinopathy in China, according to F&S. Regulatory approval for AI-based software requires product testing, detailed technology review and complex clinical trials, which are all major entry barriers for potential competitors. For example, its multi-center clinical trial with 1,000 enrolled patients validated the safety and effectiveness of Airdoc-AIFUNDUS (1.0) with sensitivity and specificity results of 91.75% and 93.10%, respectively, compared with IDX-DR, which achieved an 87.2% sensitivity rate and 90.7% specificity rate. Other versions of Airdoc-AIFUNDUS will benefit from Company's know-how and experience in bringing Airdoc-AIFUNDUS (1.0) to market, as well as benefit from the hospital and physician network Airdoc has built.

(2) Well-validated technology. Airdoc-AIFUNDUS (1.0) is developed based on Airdoc's AI-empowered retina-based early detection, diagnosis and health risk assessment technology platform, which is well-validated in terms of scientific theory, clinical trial data and clinical pathway, supported by proof-of-concept clinical trial results of an FDA-approved, MOA-equivalent product. The Company has over 20 papers published on prestigious peer-reviewed scientific journals, including the Lancet series, British Journal of Ophthalmology, British Journal of Dermatology, and presented at influential academic conferences in AI, such as MICCAI. Moreover, the outstanding performance of its products have been featured in various prestigious peer-reviewed scientific journals, including the Nature series.

Airdoc believes its AI-based early detection and diagnosis solutions could address the needs for affordable and highly-effective solutions for chronic diseases by enhancing diagnosis capabilities, improving treatment compliance, and offering non-invasive, accurate, fast, effective and scalable diagnosis solutions.

(3) Multi-brand and multi-model fundus camera compatibility to maximize market opportunities.

Airdoc-AIFUNDUS is compatible with a wide range of fundus camera brands and models due to algorithms that are built-in to achieve high adaptability. Different fundus cameras have different imaging signatures, varying in terms of brightness, color, noise level and viewing angle. The Company has trained its Airdoc-AIFUNDUS with images from various fundus cameras to ensure consistent and accurate analysis results regardless of which camera model is used. Moreover, it has utilized data enhancement to generate images with more diversity and trained Airdoc-AIFUNDUS to achieve an even higher degree of compatibility. Currently, Airdoc-AIFUNDUS (1.0) is compatible with 30 models of designated fundus camera brands including Canon, Topcon, New Vision and Suoer. In contrast, other SaMDs on the market, such as IDx-DR, are only compatible with one or a few designated fundus cameras. Airdoc believes such features could effectively address the limited medical resources available and the imbalance of its allocation in China, given Airdoc-AIFUNDUS could make the best use of the client's existing equipment and provide performance and cost-effective medical devices to detect certain chronic diseases.

(4) Effective for wider population use. Airdoc-AIFUNDUS (1.0) was trained with data from 15 different institutions in China. Its data is diverse in terms of gender, age, geographic region and other demographics, covering a high percentage of the whole population. By training Airdoc-AIFUNDUS using these data and performing multi-dimensional analysis of the product's performance on customers with different profiles, Airdoc is able to ensure that its product works consistently well for all customers, extending the applicability of its product across all markets.

(5) Automatic real-time imaging quality control. Airdoc-AIFUNDUS has an automatic quality control function with multiple independent detectors for retinal area validation, focus, color balance and exposure. The function evaluates every image captured in real time and alerts users if image quality is sub-standard, which ensures a usable image is captured before the patient leaves. Traditional quality control is reliant on the operators' experiences to evaluate the quality of a retinal image and has many drawbacks. For example, the operator may not have the professional training necessary to evaluate image quality, considerable time is needed to evaluate all images captured, and consistency in evaluation standards across different operators is difficult to maintain. Airdoc's automatic real-time imaging quality control addresses these issues by increasing accessibility and efficiency, improving the quality of diagnosis and reducing the reliance on experienced physicians.

Airdoc-AIFUNDUS (1.0)

Airdoc-AIFUNDUS (1.0), an AI-based SaMD, was the first AI-empowered retina-based auxiliary diagnosis product to obtain the Class III medical device certificate from the NMPA according to F&S, enabling it to be used in hospitals in China to assist physicians with medical diagnosis. It is approved for use by medical institutions to assist physicians in detecting diabetic retinopathy in adults. Airdoc has begun to implement its commercialization strategy for Airdoc-AIFUNDUS (1.0) since then.

Large market opportunity of Airdoc-AIFUNDUS (1.0)

Diabetes is currently on the rise with 463.0mn patients between 20 to 70 years old globally and 124.3mn patients above 18 years old in China in 2020. However, diabetes in China has a low diagnosis rate of only 43.3% and a low treatment rate of only 32.2%. According to F&S, the estimated prevalence

rate of diabetes in China grew from 9.7% in 2008 to 11.2% in 2020. Complications of diabetes include chronic or acute health problems that may affect many organ systems, cause long-lasting disability and dramatically impair quality of life. The treatment of diabetes requires extensive healthcare resources, resulting in high medical costs, which in turn places a heavy economic burden on society, patients and their families.

Diabetic retinopathy is the most common complication for patients with diabetes. Early-stage diabetic retinopathy is often asymptomatic. Regular and continuous monitoring of diabetic retinopathy could facilitate the evaluation of the progress of diabetes and therefore effectively intervene and alleviate the risks of severe complications such as vision loss, diabetic nephropathy and diabetic cardiomyopathy. Up to 30% diabetes patients, or 37.3mn people, have diabetic retinopathy in 2020 in China. Because early-stage diabetic retinopathy is often asymptomatic, approximately 90% diabetic retinopathy cases, or 33.6mn people, remain undiagnosed with a screening rate of less than 10% in China in 2020. Conventionally, diabetic retinopathy is diagnosed manually by physicians through review of retinal images captured using fundus cameras. The accurate diagnosis of diabetic retinopathy requires extensive clinical experience. However, the limited number of experienced physicians and medical equipment for diabetic retinopathy screening in China cannot meet the needs of China's growing diabetic population. As such, there is a significant need for AI-based diabetic retinopathy screening that makes use of deep learning techniques to rapidly process and analyze retinal images, supporting physicians in making diagnoses. With the assistance of AI in early diagnosis and screening of diabetic retinopathy, patients can begin to manage the chronic disease early and potentially prevent or delay disease progression. In 2020, the Guidelines for the Prevention and Treatment of Type II Diabetes Mellitus in China (2020 Edition) 《(中国2型糖尿病防治指南(2020版))》 enlisted AI-based diabetic retinopathy screening software as an effective solution to assist in the diagnosis of diabetic retinopathy and recommended using NMPA-approved AI-based medical devices for early detection and diagnosis.

As of June 13, 2021, Airdoc-AIFUNDUS (1.0), SiBionic's AIDR and Vistel's Eye Wisdom were the only three NMPA-approved AI-based SaMDs for the auxiliary diagnosis of diabetic retinopathy. As of the same date, there were two other AI-based SaMDs for auxiliary diagnosis of diabetic retinopathy approved by the FDA, being Digital Diagnostics Inc's IDx-DR and Eyenuk's EyeArt AI System. Compared with AIDR, Airdoc-AIFUNDUS (1.0) is compatible with multi-brand and multi-model fundus camera and has an automatic quality control function. Airdoc-AIFUNDUS (1.0) has demonstrated an industry-leading sensitivity and specificity during its clinical trial.

Summary of the clinical trial of Airdoc-AIFUNDUS (1.0)

Airdoc conducted a multi-center, single-set target value clinical trial to evaluate the safety and effectiveness of Airdoc-AIFUNDUS (1.0). The Company cooperated with Beijing Tongren Hospital affiliated with the Capital Medical University (首都医科大学附属北京同仁医院), the First Medical Center of China PLA General Hospital (解放军总医院第一医学中心) and Beijing Tsinghua Changgung Hospital affiliated with the Tsinghua University (清华大学附属北京清华长庚医院) to conduct its clinical trial.

The trial was designed to enroll 1,000 patients after exclusions. Participants who meet the eligibility criteria need to take two retinal fundus images of the ocular fundus (one optic disc centered, one macula centered) per eye. Airdoc-AIFUNDUS (1.0) used two images obtained from each eye of enrolled patients for analysis. Three deputy chief physicians specializing in fundus diseases with at least 10 years of experience reviewed the same images and provided reference diagnosis standards to measure the sensitivity and specificity of Airdoc-AIFUNDUS (1.0).

Trial results. The sensitivity of Airdoc-AIFUNDUS (1.0) for detecting referable diabetic retinopathy was 91.75%, which refers to the ability of Airdoc-AIFUNDUS (1.0) to correctly identify referable diabetic retinopathy cases. Airdoc-AIFUNDUS (1.0) demonstrated a 93.10% specificity, which refers to the ability of Airdoc-AIFUNDUS (1.0) to correctly identify patients without diabetic retinopathy. Airdoc-AIFUNDUS (1.0) showed a 92.67% imageability rate, demonstrating its ability to produce specialty-level diagnosis. No adverse device effect was reported.

Airdoc received the Class III medical device registration certificate from the NMPA in August 2020 and are still in the early stage of commercialization. As of June 13, 2021, Airdoc had marketed and provided Airdoc-AIFUNDUS (1.0) to two hospitals in China.

Airdoc-AIFUNDUS (2.0)

Airdoc-AIFUNDUS (2.0) is designed for the auxiliary diagnosis of hypertensive retinopathy, retinal vein occlusion and AMD. Airdoc is currently preparing for the clinical trial of Airdoc-AIFUNDUS (2.0). The Company plans to commence its multi-center clinical trial to enroll subjects in October 2021E and apply for a registration approval of new indications with the NMPA in the second quarter of 2022E. With NMPA approval of Airdoc-AIFUNDUS (2.0), it has the potential to become the first AI-based auxiliary diagnosis SaMD in China with multiple approved indications, according to F&S. As of Nov 2021, the Company commenced the multi-center clinical trial for AIFUNDUS (2.0).

Hypertensive retinopathy refers to retinal vascular damage caused by high blood pressure. When the blood pressure has been consistently high for a prolonged period, the retina's blood vessel walls may thicken. The blood vessel will become narrow, restricting blood from reaching the retina, causing vision problems. According to F&S, 13% hypertensive patients have hypertensive retinopathy in China. Hypertensive retinopathy patients in China increased from 34.8mn in 2015 to 42.2mn in 2020 and is expected to reach 62.1mn in 2030E. Diagnosis of hypertensive retinopathy is typically conducted with the help of vessel segmentation, which is an intensive task for the medical professional to conduct manually. AI-based diagnosis devices can detect hypertensive retinopathy from retinal images by analyzing the change in blood vessels using complex deep learning algorithms.

Retinal vein occlusion is a condition of eye that may cause partial or total vision loss, which is caused by a blockage in the primary vein that drains blood from the retina, or a small branch of this vein. Retinal vein occlusion may be asymptomatic, especially in early stages. Retinal vein occlusion is usually diagnosed manually by ophthalmologists using retinal imaging, fluorescein angiography and optical coherence tomography to observe the layers of the retina showing the blood vessels and how the blood is flowing through the eye. AI-based diagnosis devices may be able to analyze the fundus image and diagnose retinal vein occlusion automatically and cost-effectively.

AMD is common in people over the age of 50, which is the leading cause of vision problems. AMD affects the macula, the back part of the retina that controls central vision. As the population ages, the patient population for AMD in China is expected to increase from 26.4mn in 2020 to 52.3mn in 2030E, as per F&S. AMD has a high prevalence among people over 50 years of age, costly treatments and high disease burden, can potentially cause blindness and have a material impact on the quality of life of patients. Through deep learning algorithms trained with labeled retinal images, an AI-based AMD SaMD can identify symptoms of AMD to support the physicians in diagnosis.

As of June 13, 2021, there were no NMPA-approved products similar to Airdoc-AIFUNDUS (2.0). Airdoc believes and F&S concurs, Airdoc-AIFUNDUS (2.0) has the potential to become the first AI-based auxiliary diagnosis SaMD in China with multiple approved indications if approved by the NMPA.

As of June 13, 2021, Airdoc was preparing for the clinical trial for Airdoc-AIFUNDUS (2.0). The Company was in the process of communicating with the NMPA about its detailed clinical trial plan and protocols, including the statistical methods and clinical trial methodology. Airdoc plans to commence its multi-center clinical trial in October 2021E and begin to enroll subjects in late 2021E and apply for a registration approval of new indications with the NMPA in the second quarter of 2022E.

After obtaining the registration approval of new indications, Airdoc plans to market Airdoc-AIFUNDUS (2.0) to cardiovascular, endocrinology, neurology and ophthalmology departments in hospitals and promote it to patients with high blood pressure or at high risk of retinal vein occlusion.

Airdoc-AIFUNDUS (3.0)

Airdoc-AIFUNDUS (3.0) is designed for the auxiliary diagnosis of pathological myopia and retinal detachment. Airdoc plans to initiate the clinical trial for Airdoc-AIFUNDUS (3.0) in October 2022E.

Pathological myopia may lead to reduced vision or blindness that cannot be corrected with glasses or contact lenses. The increasing prevalence of myopia, particularly among children adolescents between 13 to 18 years old, is a cause for concern, since severe myopia can develop into pathological myopia. According to F&S, the patient population for pathological myopia in China increased from 19.2mn in 2015 to 22.6mn in 2020 at a 3.3% CAGR and is expected to reach 32.3mn in 2030E at a CAGR of 3.7% from 2020 to 2030E. In particular, the prevalence of myopia among elementary school students aged between 7 to 12 years old, middle school students aged between 13 to 16 years old and high school students aged between 16 to 18 years old in China was approximately 36%, 72%, 81%, respectively. The increasing incidence rate of pathological myopia urges the development of screening and management systems to detect the disease early to allow for potential intervention measures.

Retinal detachment is the separation of the neuroepithelium and pigment epithelium of the retina. The retinal detachment patient population in China increased is expected to reach 0.147mn in 2030E. Retinal detachment diagnosis requires experienced ophthalmologists to examine the whole retina and detect any holes or tears on the retina. However, identifying retinal detachment at an early stage is challenging because it usually starts asymptotically and develops in small increments at the retina periphery. AI-based diagnosis devices enable the efficient and automatic detection of symptoms of retinal detachment by analyzing a complete retinal image with high sensitivity and precision.

By June 13, 2021, there were no NMPA-approved products similar to Airdoc-AIFUNDUS (3.0).

As of June 13, 2021, Airdoc had finished the initial development of Airdoc-AIFUNDUS (3.0). Airdoc plans to commence its multi-center clinical trial in October 2021 and begin to enroll subjects in late 2022E and apply for a registration approval of new indications with the NMPA in the first half of 2024E. Airdoc-AIFUNDUS (3.0) targets patients with diabetes or myopia.

Glaucoma detection SaMD

Airdoc's glaucoma detection SaMD is used to process and analyze fundus images to detect glaucoma by measuring the cup to disc ratio (the "CDR") of the optic disc. The optic region is the area where the optic nerves and blood vessels enter the retina, and the cup is a small rounded depression area at the front of the optic nerve head. The CDR is a commonly used parameter in detecting glaucoma because glaucoma can cause the cup to get bigger and result in an enlarged CDR. The Company has received a Class II medical device registration certificate from the Shanghai branch of the NMPA in June 2020 and have initiated the commercialization of its glaucoma detection SaMD.

Glaucoma refers to optic nerve damage caused by pathological high pressure in the eye. It is one of the leading causes of blindness for people over the age of 45. According to F&S, the number of patients with glaucoma in China grew from 18.1mn in 2015 to 20.0mn in 2020 and is expected to reach approximately 23.0mn in 2030E. Many forms of glaucoma have no early symptoms until the gradual effects cause vision loss and cannot be reversed. Early detection could slow or prevent vision loss caused by glaucoma. The current approach for detecting glaucoma is complex, costly and time-consuming, which involves manual evaluation of the optic nerve head, visual field testing, and intraocular pressure measurements. The assessment of glaucoma is highly dependent on the physician, considering the variability of early symptoms of glaucoma. There is a significant unmet need for accurate and reproducible quantitative evaluation to detect changes due to glaucoma that is beyond normal age-related loss and short-term and long-term fluctuations. AI-based detection SaMD could help objectively and quantitatively detect glaucoma at its early stages.

Advantages of Airdoc's AI-based glaucoma detection SaMD

(1) High accuracy and objectivity. Airdoc's AI-based glaucoma detection SaMD measures CDR on retinal images and potentially reduces the variation on CDR measurement. Physicians estimate CDR using outlines of the cup and optic disc which is typically less accurate than measurement using its software. More accurate CDR measurement enables physicians to provide more accurate and objective diagnoses.

(2) Highly efficient. Compared to the conventional approach where a physician examines the outlines of the cup and optic disc and estimates the scale of cup manually, Airdoc's software can directly and automatically measure the diameter of the cup and the optic disc and conduct quantitative analysis on the CDR, which is more efficient.

(3) Easy to use. Airdoc's glaucoma detection SaMD is easy to use, enabling physicians to rely less on experience and training to generate the CDR to assist physicians in early detection of glaucoma.

(4) Editable and traceable analysis process. Airdoc's glaucoma detection SaMD can automatically identify, mark and measure outlines of the cup and optic disc, which is also editable by operators, and generate CDRs in real time. Compared to other glaucoma detection SaMD that only displays CDR results, it offers an editable and traceable analysis process with more flexibility and reliability.

Cataracts detection SaMD

Airdoc's cataracts detection SaMD is designed to detect early symptoms of cataracts by measuring the density of the lens of the eye. Airdoc had submitted the Class II medical device registration certificate application for its cataracts detection SaMD in April 2021.

Cataracts is a common eye disease that causes the lens to become cloudy or opaque, which will result in decreased vision. The lens of the eye, which is the transparent, flexible tissues located directly behind the iris and the pupil, focuses light on the retina, which sends the image through the optic nerve to the brain. If the lens is clouded by cataracts, it can no longer focus light properly and causes vision problems. An increase in lens density is an indicator of cataracts disease progression.

Among age-related eye diseases, cataracts are the leading cause of vision impairment, causing 1.2mn vision impairment cases in China 2020, according to F&S. With the aging population in China, the number of cataracts patients reached 151.5mn in 2020 and is expected to increase to 237.6mn in 2030E in China. However, a substantial proportion of cataracts remain undiagnosed with a diagnosis rate of less than 23% in China in 2020. Though surgery may be an effective way to treat cataracts, the surgery is expensive with an average cost of approximately RMB7,000 per patient.

By June 13, 2021, cataracts are diagnosed by physicians using slit-lamp bio-microscopy and graded according to established clinical scales such as LOCS III. Slit-lamp bio-microscopy requires extensive clinical expertise and therefore poses a significant challenge, particularly in rural areas where there is a shortage of trained ophthalmologists. Furthermore, subjective grading is subject to human error. Along with the growing disease burden, there is an imperative need for an automated, efficient and high performance cataracts detection method to address existing limitations and reform approaches in cataracts detection.

Advantages of Airdoc's cataracts detection SaMD

(1) Easy to use. Airdoc's cataracts detection SaMD is easy for ophthalmologists to use. Ophthalmologists will only need to select the lens area and nuclear area while its AI-based software will analyze the retinal images and grade on the LOC III scale. This lowers the reliance on ophthalmologists' manual detection, which requires extensive training and experience.

(2) Accurate detection. Airdoc's cataracts detection SaMD is an accurate and objective method to detect cataracts. The conventional approach of cataracts detection is time-consuming and cataracts severity diagnosis is subject to ophthalmologists' judgment. Its software has been trained to measure various indicators through histogram analysis results and the Company believes it conducts more accurate, data-supported grading, which helps physicians detect early symptoms of cataracts.

(3) Objective grading system. To grade the severity of cataracts, an ophthalmologist typically follows standardized but subjective grading systems. Subjective grading systems possess an inherent limitation where grading results may vary among ophthalmologists. Through the quantitative measurement of lens color and turbidity, Airdoc's software assists ophthalmologists and medical personnel to detect and grade cataracts based on LOCS III in a standardized and scalable way.

Other SaMDs for detection and diagnosis

Airdoc is developing five other SaMDs for detection and auxiliary diagnosis, covering ICVD and ASCVD, gestational diabetic retinopathy, gestational hypertensive retinopathy, papilledema intracranial hypertension retinopathy and anemia based on its AI-empowered retina-based early detection, diagnosis and health risk assessment technology platform.

ICVD and ASCVD are the most common types of cardiovascular diseases and are risk indicators for other types of cardiovascular diseases. Traditional evaluation approaches to detect and diagnose ICVD and ASCVD are intrusive, costly and time-consuming, requiring blood samples to analyze levels of glucose and blood lipids to detect and evaluate the disease. Airdoc's AI-empowered detection and diagnosis solutions not only offer non-invasive, accurate, fast, effective and scalable evaluation of ICVD and ASCVD through retinal imaging, but also provide cardiovascular health risk analysis.

Gestational diabetes and gestational hypertension are complications of pregnancy that are becoming more common. Women with gestational diabetes are at higher risk of health problems, including high blood pressure, preeclampsia (a sudden, serious increase in blood pressure), and even birth defects in the baby. Gestational diabetic retinopathy is the most common complication for pregnant women with gestational diabetes or gestational hypertension. Airdoc plans to apply for a medical device registration certificate from relevant authorities for each of its SaMD for detection and diagnosis. The Company plans to commence the clinical trial for its gestational diabetic retinopathy and gestational hypertensive retinopathy solutions in late 2024E and apply for an updated registration approval from the NMPA in early 2026E.

Papilledema intracranial hypertension retinopathy is one of the major symptoms of intracranial hypertension diseases, including cerebral hemorrhage, head trauma, cerebral edema and meningitis. These conditions will cause papilledema, which refers to optic disc swelling and blurred vision caused

by increased intracranial pressure. Traditionally, patients with intracranial hypertension are treated in the neurosurgery department, where papilledema is not a symptom that is typically considered, which could leave the symptom undiagnosed. Airdoc's AI-empowered detection and diagnosis solutions can offer neurology, neurosurgery and emergency treatment departments a non-invasive, automated and highly efficient solution to facilitate the detection, diagnosis and timely treatment of papilledema.

Anemia is a condition in which a person has a low healthy red blood cell count or the low hemoglobin and cannot carry adequate oxygen through the body. Hemoglobin is a major protein in red blood cells and a low level of hemoglobin will hamper the ability of blood to carry oxygen and may cause anemia. Symptoms of anemia include fatigue, weakness and shortness of breath. Currently, anemia is diagnosed through a blood test to count the number of red blood cells and the concentration of hemoglobin. Airdoc's AI-empowered anemia detection software enables estimation of hemoglobin levels based on retinal images in a fast and highly-effective way.

Health risk assessment solutions

Airdoc marketed AI-based health risk assessment solutions to a wide range of customers in various healthcare environments, including community clinics, health checkup centers, insurance companies, optometry centers and pharmacies. The Company's health risk assessment solutions aim to provide basic health assessment to users and enable detection of risk indicators, including retinal abnormalities, retinal vascular diseases, vitreous abnormalities, retinal tumors, optic nerve pathologies, macular diseases, congenital anomalies of the retina, cardiovascular diseases and anemia. Airdoc plans to expand the coverage of diseases and lesions of its health risk assessment solutions to include hyperthyroidism, graves ophthalmopathy, retinal vein occlusion, dementia, Parkinson's disease, atrial fibrillation and arteriosclerosis, among others.

According to the Guiding Principles of the Classification of Artificial Intelligence Medical Software Products (《人工智能医用软件产品分类界定指导原则》) and the Regulation on the Supervision and Administration of Medical Devices (《医疗器械监督管理条例》), an AI-based SaMD is regulated as a medical device if it is used to process, measure, calculate and analyze the data generated from medical devices for medical purposes, such as diagnosis or treatment, and therefore needs regulatory approval before the marketing and sales of such product. Airdoc's health risk assessment solutions are designed to be used for health management in the consumer healthcare environment and are not used for medical purposes in medical institutions, such as diagnosis or treatment. Based on the above, its PRC Legal Advisors are of the opinion that Airdoc's health risk assessment solutions will not be regulated as medical devices pursuant to the relevant PRC laws and regulations, and as a result, unlike its SaMDs for detection and diagnosis, no clinical trial, clinical evaluation or regulatory approval is required before commercialization of its health risk assessment solutions.

Health risk assessment is a white space market due to difficulties in predicting risks of developing a chronic disease compared to detection or diagnosis of an existing disease. As chronic disease prevalence in China continues to rise, demand for health risk assessment by healthcare providers and the public is growing rapidly. Airdoc has adapted its health risk assessment solutions to meet the unique needs of different healthcare customers, including health checkup centers, insurance companies, optometry centers and pharmacies. To ensure and monitor the proper use of its health risk assessment solutions, Airdoc provides various after-sales service including customer services and technical supports. In addition, if the information and retinal images uploaded to Airdoc's software cannot meet its requirements for assessment, the software program will not proceed further in order to ensure output quality.

Airdoc's health risk assessment solutions integrate its software with hardware developed by Airdoc or

third parties. Retinal images captured using fundus cameras are automatically uploaded to the cloud. The cloud platform is supported by public cloud services provided by well-known cloud service providers. Airdoc's AI algorithms then analyze the images for various risk indicators, and a report is generated with risk assessment results. In 2019 and 2020 and the three months ended March 31, 2021, its health risk assessment solutions generated revenues of RMB21.9mn/ RMB42.8mn/ RMB19.6mn, respectively.

Significant market opportunity of AI-based health risk assessment solutions

Chronic diseases, such as cardiovascular diseases and diabetes. Early detection, diagnosis and ongoing disease management are critical to controlling chronic diseases, increasing the demand for effective chronic disease management. AI-based health risk assessment solutions provide analysis on early signs and symptoms that may indicate chronic disease risk, which is a function that is in high demand and can be applied in different healthcare environments by businesses such as health checkup centers, insurance companies, optometry centers and pharmacies.

Health checkup centers offer routine checkups to detect potential chronic diseases and/or medical conditions. However, many health checkup centers need to conduct a large number of tests for comprehensive screening. Airdoc's health risk assessment solutions address the needs of health checkup centers for comprehensive, accurate, fast and highly-effective health checkup products that cover multiple diseases and lesions. Its solutions enable health risk assessment with only one quick shot of retina which is relatively low-cost and non-invasive, enabling health checkup centers to provide high-quality services and increase testing capacity.

The insurance industry involves numerous manual tasks such as customer acquisition, risk evaluation and claims processing. Leveraging AI technologies, insurance companies can optimize services and lower costs, accelerate processes and make better decisions. In particular, AI-based health risk assessment solutions could assist insurance companies to understand their customers' health conditions more accurately and efficiently. As chronic disease prevalence rises, insurance companies have a growing need to identify chronic disease risk factors, provide health management advice, offer customized insurance products and provide adequate protection.

Optometry centers in China are gradually enhancing their service capabilities to offer value-added services, such as health risk assessment, especially for vision-related health risks, to consumers and therefore have a significant need for early detection solutions to support their growing service portfolio. As of December 31, 2020, there were over 34,800 branches of optometry centers in China, according to F&S. AI-based health risk assessment products could provide a comprehensive analysis of customers' retinal environment and identify risk factors that may lead to impaired vision, which help optometry centers raise awareness for eye health, especially in younger populations.

Airdoc believes the 554,000 retail pharmacies in China are poised to become the landing point for various healthcare services in the healthcare ecosystem, gradually playing an important role in providing accessible and affordable healthcare as health management and telemedicine services increase. Pharmacies utilize AI-based health risk assessment solutions to help raise awareness for chronic diseases, provide continuous health management solutions and enhance its competitiveness and service capabilities. As their role in healthcare evolves, pharmacies will have a growing need for AI-based software solutions to support their operations.

Advantages of Airdoc's AI-based health risk assessment solutions

(1) Broad disease coverage. Airdoc's deep learning algorithms are designed to predict multiple risk factors using retinal image analysis. Its health risk assessment solutions can detect risk indicators,

which are one of the most comprehensive on the market.

(2) Powerful and industry-leading algorithms. The accuracy of Airdoc's health risk assessment solutions is measured by area under the curve (AUC), which measures the ability of the algorithm to distinguish between positive and negative cases. The higher the AUC, the better the algorithm. Its health risk assessment solutions have an average AUC of 0.968, measured on large-scale real-world user data, demonstrating accuracy compared to ground truth established by real-life medical experts' diagnoses. In cardiovascular health risk assessment, Airdoc believes its solutions also outperformed the accuracy of products published in academic papers.

(3) Outstanding real-world results. Airdoc's health risk assessment solutions have been widely deployed in many healthcare environments. In 2020, its solutions detected 2,664,398 cases and identified 328,564 cases, or 12.3% of positive features and 22,291 cases, or 0.8% of severe or urgent health problems. The Company's health risk assessment solutions have provided valuable health risk evaluation results to users and significant commercial value to consumer healthcare providers to meet their business needs.

Proprietary hardware devices

Airdoc also has three in-house developed fundus cameras compatible with its auxiliary diagnosis SaMDs and health risk assessment solutions, which enable them to provide integrated healthcare solutions that combine hardware and software. Together with Airdoc's software products, its hardware devices are powered by on-device AI technologies such as speech recognition, speech synthesis and computer vision and can successfully address pain points of existing fundus cameras on the market at a fraction of the cost.

Airdoc's AI-FUNDUSCAMERA-P is a portable, automatic and self-service fundus camera that can easily apply to any healthcare environments, which is a breakthrough innovation from existing fundus cameras. Its products are operator-free and can complete the retinal image capture automatically while traditional fundus cameras require professionals to operate. The Company received a Class II medical device certificate from the Shanghai branch of the NMPA for its AI-FUNDUSCAMERA-P in March 2021 and had commenced commercialization since then.

Airdoc's AI-FUNDUSCAMERA-D is a fully automatic and fully self-service desktop fundus camera with comparable image quality but significantly lower costs than traditional high-end desktop fundus cameras. Its infrared imaging and low-light enhancement technologies facilitate the capture of high-quality images. Its AI-FUNDUSCAMERA-D was in the research and development stage as of June 13, 2021 and Airdoc plans to apply for a Class II medical device registration certificate in the second quarter of 2022E.

Developed based on AI-FUNDUSCAMERA-P and AI-FUNDUSCAMERA-D, Airdoc's AI-FUNDUSCAMERA-M is a multimodal health scanner integrated with more biosensors that enable it not only to capture retinal images but also other physiological data, such as electrocardiograms, blood oxygen and blood pressure. The collection of multimodal physiological data serves as the foundation of its AI-based health risk assessment solutions. The Company expects to apply for a Class II medical device registration certificate for its AI-FUNDUSCAMERA-M in the fourth quarter of 2023E.

Overview of deep learning AI technology

Artificial intelligence (AI) is a branch of computer science that aims to emulate human intelligence through intelligent systems such as image analysis and speech recognition. Machine learning is a subset of AI focused on building applications that enables machines to learn from data or experiences without being explicitly programmed. Machine learning uses algorithms to extract knowledge from large amounts of data. It uses large amounts of structured and semi-structured data to generate accurate predictions.

Deep learning, widely considered to be “scalable machine learning”, is a subset of machine learning which refers to algorithms developed to mimic the neuronal connectivity of the human brain to perform intelligent tasks, including complex tasks such as analyzing medical images for early detection and diagnosis of chronic diseases. Deep learning distinguishes itself from machine learning by how the algorithms learns and the amount of data it uses. Machine learning algorithms rely on human intervention to determine the hierarchy of features to understand the differences between data inputs and it usually learns from large amount of structured data. Deep learning automates the progress of feature extraction, eliminate most of the human intervention, and allows the use of massive amounts of data to improve its accuracy.

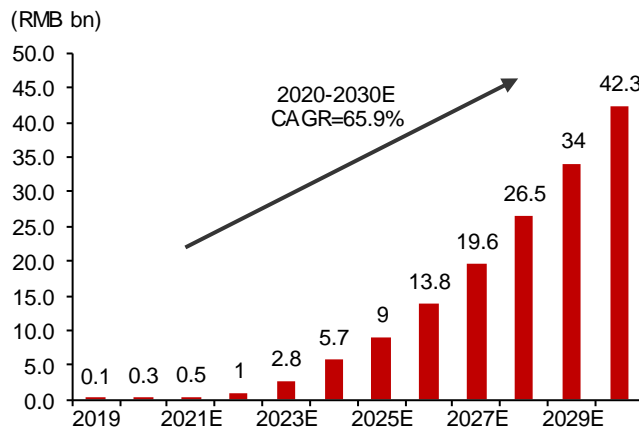
AI-based medical imaging market in china

Advancements in AI technologies, especially deep learning technologies, have driven the integration of AI in the healthcare industry. With the ability to analyze large volumes of complex data by learning from real-world feedback, AI technologies have been increasingly applied to medical imaging in various applications, including early detection, diagnosis and health risk assessment. Compared to traditional medical imaging, AI-based medical imaging enables a non-invasive, accurate, fast, effective and scalable solution to detect, diagnose and assess risks to address various healthcare needs for the whole population.

According to F&S, China’s AI-based medical imaging market is expected to increase from RMB0.3bn in 2020 to RMB92.3bn in 2030E at a 76.7% CAGR from 2020 to 2030E. AI-based medical imaging is used in medical institutions primarily to assist physicians with disease detection and diagnoses, and accounts for approximately 86% of the AI-based medical imaging market in 2020.

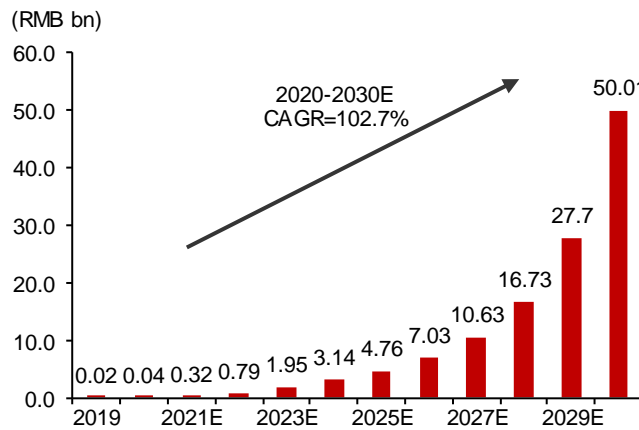
AI-based medical imaging is used in consumer healthcare environments primarily for health risk assessment. Due to the unmet needs of providing accessible and continuous health management solutions in consumer healthcare environments, AI-based medical imaging in consumer healthcare environments is a white space segment and is expected to experience faster growth compare to AI-based medical imaging in medical environments at a 102.7% CAGR from 2020 to 2030E.

Figure 10: PRC AI-based medical imaging market size (medical institutions)



Source: F&S, CMBIS

Figure 11: PRC AI-based medical imaging market size (consumer healthcare environment)

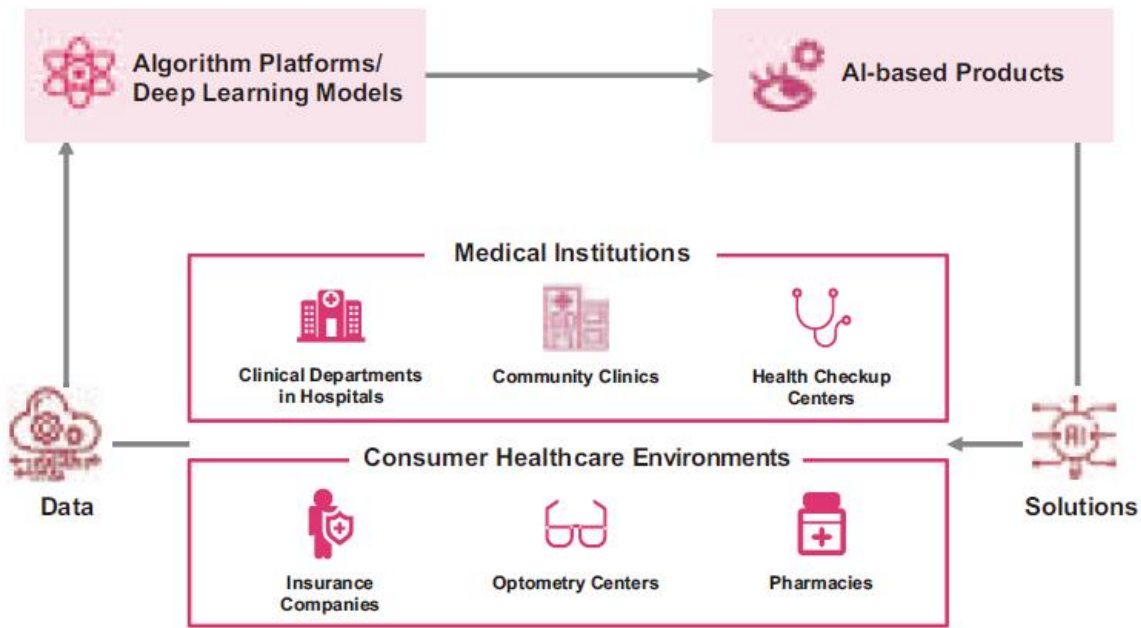


Source: F&S, CMBIS

The AI-based medical imaging ecosystem

AI-based medical imaging solution providers and solution users are key stakeholders in the AI-based medical imaging virtuous cycle. Providers of AI-based medical imaging solutions, including algorithm platforms, hardware devices, services and infrastructures, rely on a massive input of real-world data to train their algorithms, improve the hardware devices, optimize the services performances and apply these algorithms in various healthcare environments to find the abnormalities and patterns in images and identify specific markers. Solution users, including hospitals, health checkup centers, insurance companies, optometry centers and pharmacies, who provide these solutions to end-users, use these solutions to analyze input medical images to be used in these solutions for disease detection, diagnosis or risk assessment to serve end customers. When these medical images are analyzed by the AI-based solutions, they can help optimize the deep learning algorithms of the solutions, hardware device designs and service infrastructures, creating a virtuous cycle of data collection, technology optimization and solution enhancement.

Figure 12: Virtuous cycle of data collection, technology optimization and solution enhancement



Source: F&S, CMBIS

AI-based retinal imaging in China

Emerging AI-based retinal imaging market

The retina is the light-sensitive layer at the back of the eye that triggers nerve impulses and transmits such impulses to the brain through the optic nerve. It is the only part of the human body where both blood vessels and nerve cells can be directly observed in a non-invasive manner. Changes in blood vessels and nerve cells can be indicators of various chronic diseases. Retinal imaging is therefore used to directly observe and analyze blood vessels and nerve cells to detect, diagnose and assess risks of chronic diseases, including ocular diseases, such as diabetic retinopathy, pathological myopia, retinal vein occlusion, glaucoma and AMD, as well as other chronic diseases, including hypertension, diabetes, ICVD, Parkinson's disease and anemia.

AI-based retinal imaging is developed based on deep learning algorithms, analyzing retinal images and classifying them by disease and lesion. The manifestation of a disease in the retina is difficult to be detected in the early stage, especially manually by physicians. With the help of high-precision AI-based retinal imaging and analysis, subtle changes due to the disease can now be detected. AI-based retinal imaging has experienced the fastest growth in the AI-based medical imaging market. Starting from 2015, IBM Watson and Google DeepMind introduced AI technologies to analyze key anomalies in retinal images, including AMD, diabetic retinopathy and glaucoma. Since 2014, AI-based retinal imaging began to develop in China with new market players emerging and began to expand from single disease screening to comprehensive diagnosis of various diseases and lesions.

The emerging AI-based retinal imaging market is driven by:

Imbalanced allocation of medical resources and shortage of experienced physicians. The aging population and increasing prevalence of chronic diseases in China over the last decade have paved the way for huge demand for AI medical imaging in China. Different from acute or incurable diseases, chronic diseases need long-term, routine and scientific management, and can result in a heavy economic burden on society, patients and their families if not addressed with effective and timely disease management. Detection and diagnosis of chronic diseases in their early stage enables prompt treatment that can slow or prevent disease development and reduce costly health outcomes. However, this has not been possible on a nationwide scale due to the imbalanced allocation of medical resources and the shortage of experienced physicians. AI-based retinal imaging can address these needs by offering non-invasive, accurate, fast, effective and scalable chronic disease early detection and ongoing management solutions and lower reliance on specialized and experienced physicians.

Technology upgrades and innovation. The continued development and optimization, and increased application of deep learning technology, has the potential to transform healthcare by enabling highly efficient and highly scalable detection, diagnosis and risk assessment for the whole population. Recently development of deep learning algorithms has attained impressive performance in many fields such as image classification, object detection and semantic segmentation. The performance of these deep learning algorithms has begun to exceed human performance in many tasks. Human top-5 classification error rate on the large scale ImageNet dataset has been reported to be 5.1%, whereas a deep learning algorithm achieves a top-5 error rate of 3.57%. AI-based medical imaging and the adoption of deep learning algorithms enable outstanding solutions for image classification by disease type, lesion detection and lesion segmentation. For example, the CheXNet models developed by Stanford University exceeds the average radiologist performance on the pneumonia detection test and achieved F1 score of 0.435 (95% CI 0.387, 0.481), higher than the radiologist average of 0.387 (95% CI 0.330, 0.442). With the improvement and advances in AI-based medical imaging, AI-based retinal imaging could provide an efficient solution that augments human intelligence in healthcare, with the use of algorithms in the analysis of complex medical data to provide useful diagnostic outputs.

Increasing government expenditure and policy support for AI-based medical imaging. Since 2016, the PRC government had promulgated a series of laws and regulations to promote the development of AI-based medical imaging in China. For example, the NMPA updated the Medical Device Classification Catalogue (《医疗器械分类目录》) to include AI medical devices as Class II or Class III medical devices. In July 2019, the NMPA published the Evaluation Guidelines for Deep Learning Assisted Decision-Making Medical Device Software (《深度学习辅助决策医疗器械软件审评要点》), which further clarifies the clinical trial requirements and approval procedures for deep learning-based medical devices. In 2020, AI-based diabetic screening software included in the Guidelines for the Prevention and Treatment of Type II Diabetes Mellitus in China (2020 Edition) (《中国2型糖尿病防治指南(2020版)》), serving as strong recognition and validation of AI-based diabetic retinopathy screening for the prevention and treatment of diabetes.

Growing capital support. The healthcare industry has become a major application for AI technologies with the investors recognizing the enormous potential that AI solutions can offer for improving the quality of healthcare services, expanding the reach of healthcare services and reducing healthcare costs. From 2015 to 2020, investments in China's AI-based medical imaging market increased from RMB0.5bn in 2015 to RMB3.5bn in 2020 at a CAGR of 45.3%. Initial capital injections play a vital role in the formation of the AI-based retinal imaging market. Because the market of AI-based medical devices is still nascent, growing capital support will keep driving the development of AI technologies to reform the traditional methods to cut costs, improve treatment, and boost accessibility of healthcare.

Advantages of AI-based retinal imaging

In China, AI-based retinal imaging is more and more being used in medical institutions, including hospitals, community clinics and health checkup centers, and consumer healthcare environments, such as insurance companies, optometry centers and pharmacies.

Medical institutions

Compared with traditional retinal imaging approaches, AI-based retinal imaging has the following advantages:

(1) Diagnosis efficiency. AI-based retinal imaging can independently complete preliminary screening within a short duration and send results to the doctor for final diagnosis, shortening the doctor's image analysis time and improving diagnosis efficiency.

(2) Mitigate the imbalance of medical resources. AI-based retinal imaging could lower the need for extensive healthcare resources for the treatment of chronic diseases by offering patients more medical opportunities and improved diagnosis capabilities in regions where medical resources are limited or unavailable. Therefore, this reduces the heavy economic burden on society, patients and their families.

(3) Diagnostic accuracy. AI-based medical imaging has the potential to enhance image recognition in ways that allow for more efficient and accurate diagnoses and more effective use of highly skilled physicians. By enhancing diagnostic throughput and accuracy, healthcare systems can improve physicians' productivity and help enable physicians to handle a wider range of medical image analysis tasks. With greater diagnostic efficiency and efficacy, patients may be able to avoid unnecessary checks and receive treatment more quickly when it is needed. These results can help improve patient outcomes, increase patient and clinician satisfaction, and contribute to lower healthcare costs.

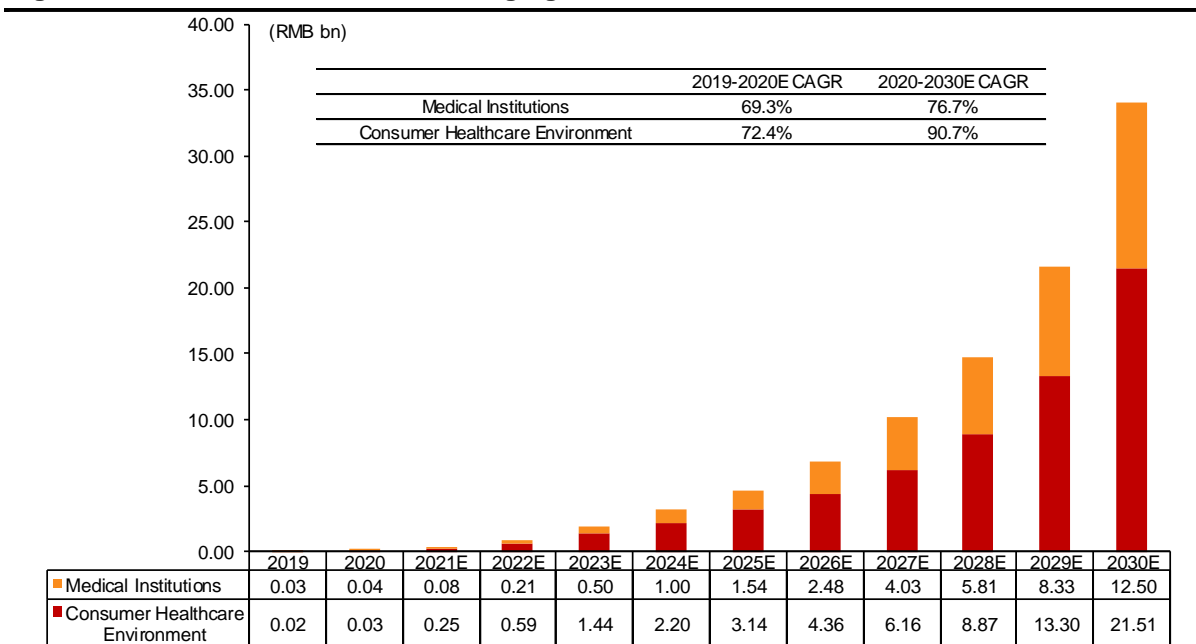
Consumer healthcare environment

(1) Health risk management. AI-based retinal imaging could fulfill the unmet need for health risk

assessment by providing accessible and continuous health management. Medical institutions currently do not have enough capacities to provide such healthcare services and therefore creating opportunities for AI-based health risk assessment solutions in consumer healthcare environments.

(2) Comprehensive and customized products and services. AI-based retinal imaging is developed and optimized based on the consumer healthcare customer's needs and accommodate the unique features for their businesses, which could fulfill the needs of consumer healthcare customers to enhance their service capabilities to offer value-added services, such as health risk assessment.

Figure 13: AI-based retinal medical imaging market size, 2019-2030E



Source: F&S, CMBIS

AI-based retinal imaging market potential by disease type

Many chronic diseases, such as diabetes, hypertension, and cardiovascular and cerebrovascular conditions, leave telltale clues of their presence in the retina. By detecting these clues using retinal imaging technologies, physicians can treat the underlying diseases earlier, more successfully, and at a lower cost.

Endocrinology diseases

Diabetic retinopathy is one of the severe complications of diabetes, caused by high blood sugar levels that damage the retina. Early-stage diabetic retinopathy is often asymptomatic. With the increasing prevalence of diabetes in China, the diabetic retinopathy patient population in China increased from 32.5mn in 2015 to 37.3mn in 2020 with a 2.8% CAGR and is forecasted to reach 50.6mn in 2030E at a CAGR of 3.1% from 2020 to 2030E, as per F&S. Regular and continuous monitoring of diabetic retinopathy could facilitate the evaluation of the progress of diabetes and therefore effectively intervene and alleviate the risks of severe complications such as vision loss, diabetic nephropathy and diabetic cardiomyopathy. As such, there is a significant need for AI-based diabetic retinopathy screening that makes use of AI technologies such as deep learning algorithms to rapidly process and analyze retinal images, supporting physicians in making diagnoses. According to F&S, the market size of the diabetic retinopathy screening market in China reached RMB2.2bn in 2020 and will reach RMB10.0bn in 2030E at a CAGR of 16.6% from 2020 to 2030E.

Cardiac diseases

(1) Hypertensive retinopathy is retinal vascular damage caused by hypertension. Hypertension is one of the most common chronic diseases in China with over 324.4mn patients in 2020. Hypertensive retinopathy is considered to be one of the most significant factors to detect and monitor severe hypertension. Hypertensive retinopathy patients should conduct retinal screening one to two times a year according to the severity of their conditions. However, less than 15.0% of hypertensive patients conduct regular checkups, which leads to an increase of hypertensive retinopathy patient population in China from 34.8mn in 2015 to 42.2mn in 2020 with a 3.9% CAGR. The market size of hypertensive retinopathy screening in China reached RMB8.8bn in 2020 and is forecasted to reach RMB27.0bn in 2030E at a CAGR of 11.9% from 2020 to 2030E, as per F&S.

(2) Retinal vein occlusion is a condition of eye that may cause partial or total vision loss, which is caused by a blockage in the primary vein that drains blood from the retina, or a small branch of this vein. Retinal vein occlusion may be asymptomatic, especially in early stages. According to F&S, the retinal vein occlusion patient population in China increased from 5.6mn in 2015 to 6.7mn in 2020 with a 3.7% CAGR and will reach 9.5mn in 2030E at a CAGR of 3.5% from 2020 to 2030E.

Eye diseases

(1) Pathological myopia. The increasing prevalence of myopia, particularly among adolescence between age 13 to 18 is a cause for concern, since severe myopia can develop into pathological myopia. Unlike myopia, pathological myopia is accompanied by degenerative changes in the retina, which can lead to irrecoverable vision loss if left untreated. According to F&S, the pathological myopia patient population in China increased from 19.2mn in 2015 to 22.6mn in 2020 with a 3.3% CAGR and will reach 32.3mn in 2030E at a CAGR of 3.7% from 2020 to 2030E. The increasing prevalence of pathological myopia, especially among adolescence between age 13 to 18, urges the development of screening and management systems to detect the disease early to allow for potential interventional measures.

However, current methods of detection remain highly reliant on visual acuity testing, fundus examination and axial length measurement, which are manual, time-consuming and subjective on a case-by-case basis, and may be particularly unreliable in young patients. There is hence a great need to objectively and automatically detect the presence and track the progress of pathologic myopia. In August 2018, pathological myopia was included in the Implementation Plan for Comprehensive Prevention and Control of Myopia among Children and Adolescents (《综合防控儿童青少年近视实施方案》) serving as strong attention of government policies.

(2) Age-related macular degeneration (AMD) is one of the most common eye diseases that can cause permanent visual impairment, which mainly occurs in people over the age of 50. Without timely treatment, AMD may cause blindness and materially impact the quality of life of patients. Because AMD rarely causes symptoms in its early stages, early detection of treatable AMD is the key to reducing the risk of progressing to more advanced AMD and to avoid vision loss. The AMD patient population in China increased from 15.7mn in 2015 to 26.4mn in 2020 with a 11.0% CAGR and is forecasted to reach 52.3mn in 2030E at a CAGR of 7.1% from 2020 to 2030E, as per F&S.

(3) Retinal detachment is the separation of the neuroepithelium and pigment epithelium of the retina. The risk of developing a retinal detachment is five or six times greater in people with high myopia compared to those with low myopia. People with high myopia have longer eyes (axial elongation), which means that the retina is more stretched and therefore prone to peripheral retinal tears. Without timely diagnosis and treatment, patients may experience irreversible vision loss. Retinal detachment diagnosis requires experienced ophthalmologists to examine the whole retina and detect any holes or

tears on the retina, which is challenging because retinal detachment usually starts asymptotically and develops in small increments at the retina periphery. AI-based diagnosis devices enable the efficient and automatic detection of retinal detachment by analyzing a complete retinal image with high sensitivity and precision. The retinal detachment patient population in China reached 0.14mn in 2020 and is forecasted to reach 0.15mn in 2030E at a CAGR of 0.4% from 2020 to 2030E, as per F&S.

High entry barriers in AI-based medical imaging market

There are significant entry barriers and challenges in the AI-based medical imaging market and AI-based retinal imaging market in China.

Real-world retinal image data

High-quality retinal image data is the key to develop and further improve the deep learning algorithms used in AI-based medical imaging. A massive amount of real-world medical images is required to continuously train the deep learning models to accurately pinpoint conditions relates to diseases. In general, the more the data, the better the model's performance is. In addition, retina-based clinical data need to be labeled by medical experts to train deep learning algorithms. New entrants may not be able to accumulate sufficient medical image data with high quality labels.

Deep learning algorithms development

Deep learning algorithms serve as the key to developing an AI-based medical device. Such development is a complex and time-consuming process. New entrants may lack the in-depth expertise and experiences required for developing the deep learning algorithms.

Stringent regulation

In recent years, the PRC government has consistently enhanced the supervision of research and development, manufacturing and distribution of medical devices. For example, if an AI-based medical device is regulated as Class III medical device, it is subject to a series of regulations issued by the NMPA and an NMPA approval is needed for its commercialization. Before a company could apply for a registration certificate from the NMPA, it needs to conduct extensive pre-clinical studies and clinical trials to prove the safety and effectiveness of the product. Generally, it takes a long time for new entrants to obtain the NMPA approval and the length of time could be unpredictable.

Research and development capabilities

The research and development of AI-based medical imaging is a complex process and often requires professional, scientific expertise and knowledge in the field of deep learning, medicine, computer vision, data analytics, Internet service, medical device and biology and sustained funding for its improvement. The talent pool for AI-based medical imaging market, especially those with multi-disciplinary backgrounds and experience, is very limited. AI-based medical imaging companies need to recruit a team of talented and experienced industry experts, which is usually challenging for new entrants to build up such a team in a relevantly short period.

Market awareness and reputation

AI-based retinal imaging is newly introduced into China, which needs lots of market education and promotion to familiarize physicians and medical institutions and improve their willingness to adopt this new technology. It is usually challenging for new entrants to establish market awareness and reputation, such as entering into collaborations with medical institutions or academic institutions to commence marketing and promotion activities. This process may take a long time and involve significant uncertainty.

Intensive capital investment

A large amount of investment is required for the launch of a new medical device. Research and development of software and hardware, the onboarding of internal and external medical experts and the conducting of clinical trials all necessitate significant capital investments. Once a research and development program progress into late-stage clinical development, an even greater amount of capital is needed for the preparation and execution of commercialization.

Competitive landscape of AI-based retinal imaging industry

In China and globally, AI-based medical devices have been utilized in healthcare environments for a number of years. At present, other than Airdoc-AIFUNDUS (1.0), which has been approved by the NMPA in China for auxiliary diagnosis of diabetic retinopathy, AIDR and Eye Wisdom screening are the two only products of the same kind that has been approved by the NMPA. In US, IDx-DR and EyeArt are the only two SaMDs which have been approved by the FDA for auxiliary diagnosis of diabetic retinopathy.

Figure 14: Competitive landscape - AI-based retinal imaging products/software

Company	Registered Product	Issuing Agency	Approved Date	Other AI-based Retinal Imaging Products	Indications	Self-developed Hardware	Commercialization
Airdoc	Airdoc-AIFUNDUS (1.0)	NMPA	August 2020	<ul style="list-style-type: none"> Airdoc-AIFUNDUS (2.0) Airdoc-AIFUNDUS (3.0) Individual SaMDs Health Risk Assessment Solutions 	<ul style="list-style-type: none"> SaMDs: Auxiliary diagnosis of various diseases including diabetic retinopathy, hypertensive retinopathy, retinal vein occlusion, age related macular degeneration (AMD), cataract, retinal detachment, pathological myopia and glaucoma, ICVD/ASCVD, etc. Health risk assessment solutions: assess health risk indicators related to various diseases and lesions 	Yes	Medical institutions and consumer healthcare environments
		CE	March 2020				
Tencent	/	/	/	<ul style="list-style-type: none"> Tencent Miying's AI 	<ul style="list-style-type: none"> Diabetic retinopathy 	No	N/A
Baidu	/	/	/	<ul style="list-style-type: none"> AI Fundus Camera 	<ul style="list-style-type: none"> Diabetic retinopathy, macular degeneration and glaucoma 	No	N/A
SiBionics	AIDR Screening	NMPA	August 2020	/	<ul style="list-style-type: none"> Diabetic retinopathy 	No	Medical institutions
Vistel	EyeWisdom (1.0)	NMPA	June 2021	/	<ul style="list-style-type: none"> Diabetic retinopathy 	No	Medical institutions
		CE	January 2020				
Google	/	/	/	<ul style="list-style-type: none"> Projects around Diabetic Retinopathy 	<ul style="list-style-type: none"> Diabetic retinopathy and diabetic macular edema 	No	N/A
IBM	/	/	/	<ul style="list-style-type: none"> IBM's Deep Learning Technology 	<ul style="list-style-type: none"> Diabetic retinopathy 	No	N/A
Digital Diagnostics Inc	IDx-DR	FDA	April 2018	/	<ul style="list-style-type: none"> Diabetic retinopathy and diabetic macular edema 	No	Medical institutions
		CE	April 2016				
Eyenuk	EyeArt AI System	FDA	August 2020	<ul style="list-style-type: none"> Eyenuk's Glaucoma Software 	<ul style="list-style-type: none"> Diabetic retinopathy, glaucoma and AMD 	No	Medical institutions
		CE	June 2016	<ul style="list-style-type: none"> Eyenuk's AMD Software 			

Source: F&S, CMBIS

Financial analysis

Revenue to deliver 102.4% CAGR in FY21-24E

We expect total revenue to grow 148%/ 102%/ 89%/ 77% YoY to RMB118mn/ RMB239mn/ RMB451mn/ RMB799mn in FY21E/ 22E/ 23E/ 24E, mainly driven by the fast-growing provisions of AI-based software solutions.

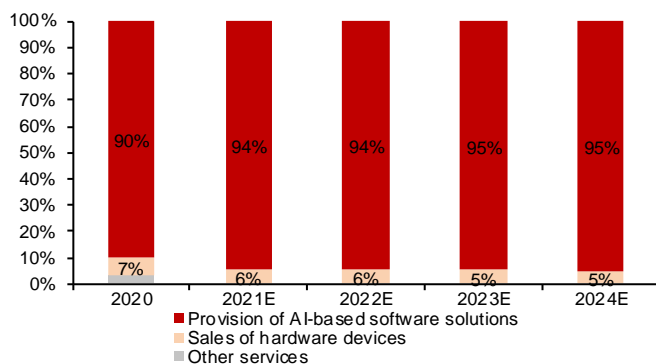
We expect the AI-based software solutions will contribute the most revenue to the Company. We forecast the revenue of the AI-based software solutions to grow 160%/ 102%/ 90%/ 78% YoY to RMB111mn/ RMB225mn/ RMB427mn/ RMB761mn, accounting for 94%/ 94%/ 95%/ 95% of the total revenue in FY21E/ 22E/ 23E/ 24E, respectively.

Figure 15: Revenue forecasts (2021E-2024E)

(RMB mn)	2020	2021E	2022E	2023E	2024E
Provision of AI-based software solutions	43	111	225	427	761
YoY	96%	160%	102%	90%	78%
Sales of hardware devices	3	7	13	24	38
YoY	0%	100%	100%	80%	60%
Other services	1	0	0	0	0
YoY	-72%	-100%	N/A	N/A	N/A
Total revenue	48	118	239	451	799
YoY	57%	148%	102%	89%	77%

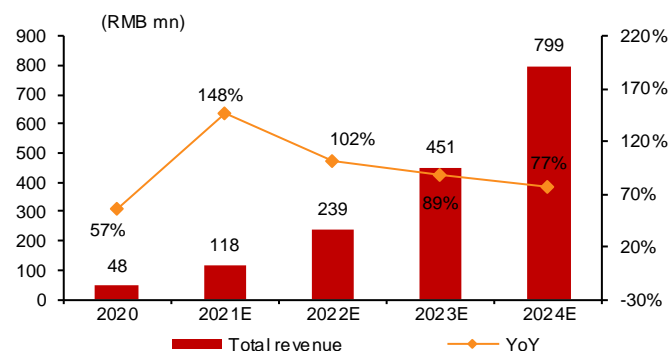
Source: PHIP, CMBIS estimates

Figure 16: Revenue breakdown



Source: PHIP, CMBIS estimates

Figure 17: Total revenue and growth forecasts



Source: PHIP, CMBIS estimates

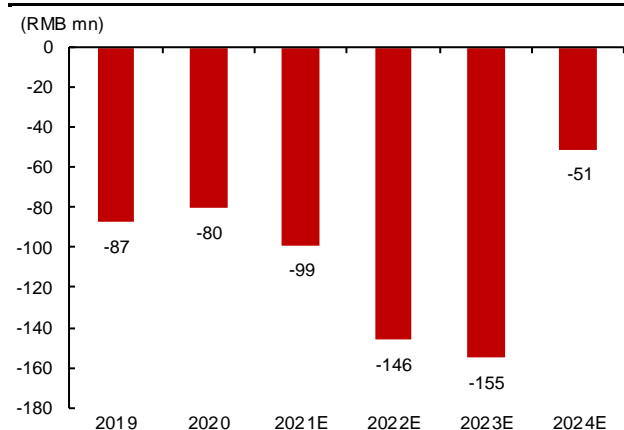
Airdoc recorded net losses of RMB87mn/ RMB80mn in FY19A/20A. We expect it to continue incur net loss of RMB99mn/ RMB146mn/ RMB155mn / RMB51mn in FY21E/ 22E/ 23E/ 24E and we expect the Company to generate net profit from FY25E.

Figure 18: P&L forecasts

(YE 31 Dec) (RMB mn)	2020	2021E	2022E	2023E	2024E
Revenue	48	118	239	451	799
YoY	56.7%	147.6%	102.1%	89.1%	77.2%
Cost of services	(19)	(44)	(76)	(121)	(196)
% of revenue	-39.0%	-36.9%	-31.9%	-26.8%	-24.5%
Gross profit	29	74	162	330	604
GPM	61.0%	63.1%	68.1%	73.2%	75.5%
Selling & marketing expenses	(26)	(59)	(95)	(144)	(216)
% of revenue	-54.1%	-50.0%	-40.0%	-32.0%	-27.0%
Administrative expenses	(18)	(41)	(72)	(104)	(128)
% of revenue	-37.6%	-35.0%	-30.0%	-23.0%	-16.0%
Research and development expenses	(42)	(83)	(155)	(248)	(320)
% of revenue	-89%	-70%	-65%	-55%	-40%
Other Income	5	10	14	11	9
% of revenue	10.5%	8.2%	5.8%	2.5%	1.1%
Operating profit	(52)	(99)	(146)	(155)	(51)
% of revenue	-108.9%	-83.7%	-61.1%	-34.3%	-6.4%
Finance costs	(0)	(0)	(0)	(0)	(0)
% of revenue	0.0%	0.0%	0.0%	0.0%	0.0%
Changes in the carrying amount of financial instruments	(27)	0	0	0	0
% of revenue	-57.3%	0.0%	0.0%	0.0%	0.0%
Profit before tax	(79)	(99)	(146)	(155)	(51)
PBT margin	-166.2%	-83.7%	-61.1%	-34.3%	-6.4%
Income tax expense	(0)	0	0	0	0
% tax rate	-0.5%	0.0%	0.0%	0.0%	0.0%
Total net profit	(80)	(99)	(146)	(155)	(51)
Minority Interests	0	0	0	0	0
Net profit attributable to shareholders	(80)	(99)	(146)	(155)	(51)
NMP	-167.9%	-83.7%	-61.1%	-34.3%	-6.4%

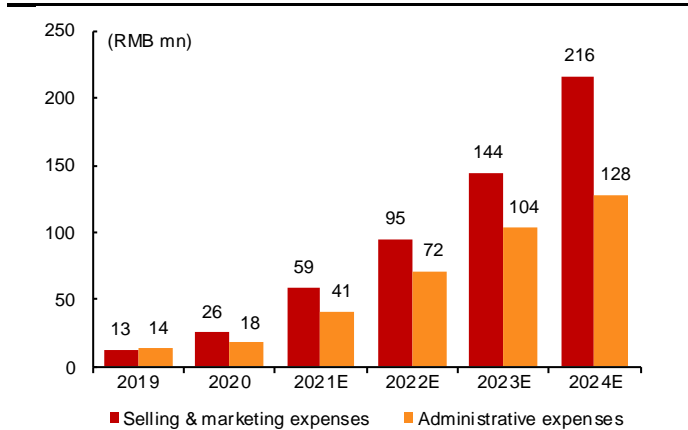
Source: PHIP, CMBIS estimate

Figure 19: Net profit forecasts (2019-2024E)



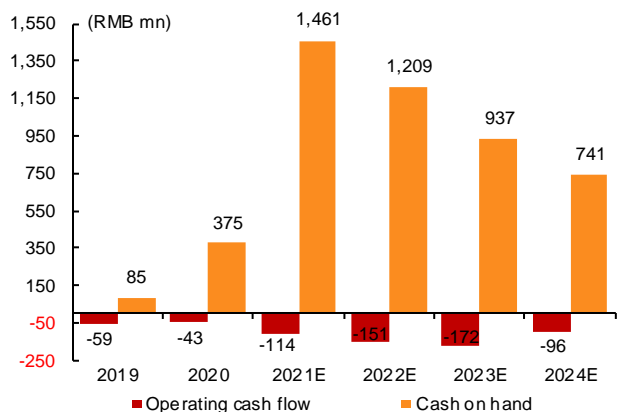
Source: PHIP, CMBIS estimates

Figure 20: SG&A expenses forecasts (2019-2024E)



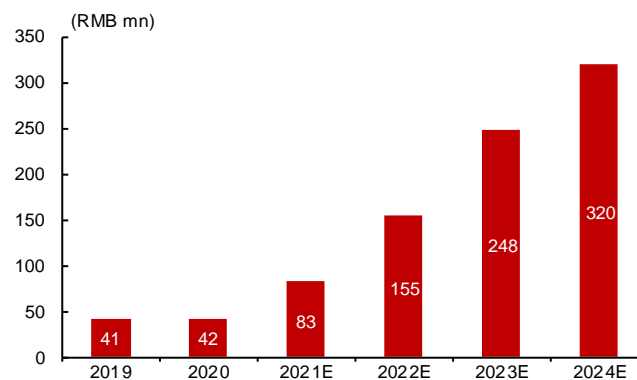
Source: PHIP, CMBIS estimates

Figure 21: Cash on hand and operating cash flows



Source: PHIP, CMBIS estimates

Figure 22: R&D expenses (2019-2024E)



Source: PHIP, CMBIS estimates

Financial statements

Income statement

YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue	30	48	118	239	451
Provision of AI-based software	22	43	111	225	427
Sales of hardware devices	3	3	7	13	24
Other services	5	1	0	0	0
Cost of sales	-14	-19	-44	-76	-121
Gross profit	16	29	74	162	330
R&D expenses	-41	-42	-83	-155	-248
Selling & marketing expenses	-13	-26	-59	-95	-144
Administrative expenses	-14	-18	-41	-72	-104
Other Income	6	5	10	14	11
Operating profit	-46	-52	-99	-146	-155
Finance costs	0	0	0	0	0
Changes in the carrying amount of financial instruments to investors	-41	-27	0	0	0
Profit before tax	-87	-79	-99	-146	-155
Income tax expense	-0	-0	0	0	0
Total net profit	-87	-80	-99	-146	-155
Minority Interests	-0	0	0	0	0
Profit attributable to shareholders	-87	-80	-99	-146	-155

Cash flow summary

YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Profit before tax	-87	-79	-99	-146	-155
D&A	3	5	6	29	47
Impairment	1	0	0	0	0
Change in working capital	-14	-4	-21	-35	-65
Other operating activities	38	35	0	0	0
Income tax paid	0	0	0	0	0
Net cash from operating	-59	-43	-114	-151	-172
Purchase of PP&E	-2	-22	-100	-100	-100
Investment in unlisted equity	0	-2	0	0	0
Other investing activities	-25	116	0	0	0
Net cash from investing	-27	92	-100	-100	-100
Capital contributions	4	63	1,300	0	0
Proceeds from bank borrowings	0	0	0	0	0
Other financing activities	58	178	0	0	0
Net cash from financing	61	241	1,300	0	0
Net change in cash	-24	289	1,086	-251	-273
Cash at the beginning year	109	85	375	1,461	1,209
Effects of exchange rate	0	0	0	0	0
Cash at the end of the year	85	375	1,461	1,209	937

Balance sheet

YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Non-current assets	6	27	121	192	245
Property, plant and equipment	6	23	117	188	241
Other financial assets	0	4	4	4	4
Current assets	233	409	1,510	1,307	1,117
Inventories	0	4	7	13	20
Trade receivables	17	20	39	78	148
Prepayments and other receivables	41	11	3	7	12
Cash and cash equivalents	85	375	1,461	1,209	937
Other financial assets	90	0	0	0	0
Current liabilities	396	25	19	32	51
Trade payables	22	17	11	19	30
Contract liabilities	6	7	7	13	20
Lease liabilities	1	1	1	1	1
Other current liabilities	368	0	0	0	0
Non-current liabilities	2	2	2	2	2
Deferred income	2	2	2	2	2
Borrowings	0	0	0	0	0
Total equity	-159	408	1,610	1,464	1,309
Issued capital	12	75	75	75	75
Reserves	-171	333	1,534	1,389	1,234
Non-controlling interests	0	0	0	0	0

Key ratios

YE 31 Dec	FY19A	FY20A	FY21E	FY22E	FY23E
Sales mix (%)					
Provision of AI-based	71.8	89.9	94.3	94.4	94.7
Sales of hardware devices	11.0	7.0	5.7	5.6	5.3
Other services	17.2	3.1	0.0	0.0	0.0
Total	100.0	100.0	100.0	100.0	100.0
Profit & loss ratios (%)					
Gross margin	53	61	63	68	73
EBITDA margin	-277	-157	-87	-54	-26
Pre-tax margin	-286	-166	-84	-61	-34
Net margin	-286	-168	-84	-61	-34
Effective tax rate	0	0	0	0	0
Balance sheet ratios					
Current ratio (x)	0.59	16.42	80.27	40.61	22.08
Inventory days	0	70	60	60	60
Trade receivables turnover	198	150	120	120	120
Trade payable days	555	377	90	90	90
Net gearing ratio	0.53	Net cash	Net cash	Net cash	Net cash
Returns (%)					
ROE	N/A	-19.5	-6.1	-10.0	-11.8
ROA	N/A	-18.3	-6.1	-9.7	-11.4
Per share value					
EPS (RMB)	N/A	N/A	-0.95	-1.41	-1.50
DPS (RMB)	N/A	N/A	0.00	0.00	0.00
BVP (RMB)	N/A	N/A	15.54	14.13	12.64

Source: PHIP, CMBIS estimates

Valuation

TP of HK\$95.32 based on DCF model

Given that Airdoc will mainly rely on future commercialization of AI-based software solutions, we believe DCF would be a reasonable method to value the Company. We derive TP of HK\$95.32 based on a 10-year DCF model (WACC:11.4%, terminal growth rate: 3.0%).

Figure 23: Base case valuation on DCF valuation

DCF Valuation (in RMB mn)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	-108	-159	-166	-59	169	464	731	1,062	1,420	1,789
Tax rate	0.0%	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
EBIT*(1-tax rate)	-108	-159	-166	-59	144	394	621	903	1,207	1,520
+ D&A	6	29	47	60	70	78	83	87	91	93
- Change in working capital	-21	-35	-65	-106	-107	-168	-129	-148	-126	-90
- Capex	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100
FCFF	-223	-265	-283	-205	7	204	475	742	1,072	1,424
Terminal value										17,484
Terminal value (RMB mn)	5,947									
Total PV (RMB mn)	6,734									
Net debt (RMB mn)	-1,460									
Minority interest (RMB mn)	0									
Equity value (RMB mn)	8,194									
Equity value (HK\$ mn)	9,872									
# of shares (mn)	104									
Price per share (HK\$ per share)	95.32									
Terminal growth rate	3.0%									
WACC	11.4%									
Cost of Equity	13.8%									
Cost of Debt	5.0%									
Equity Beta	0.9									
Risk Free Rate	4.0%									
Market Risk Premium	10.5%									
Target Debt to Asset ratio	25.0%									
Effective Corporate Tax Rate	15.0%									

Source: CMBIS estimates

Figure 24: Sensitivity analysis (HK\$)

Terminal growth rate	WACC				
	10.4%	10.9%	11.4%	11.9%	12.4%
2.0%	102.37	94.38	87.35	81.12	75.58
2.5%	107.51	98.76	91.11	84.37	78.40
3.0%	113.35	103.70	95.32	87.98	81.52
3.5%	120.04	109.31	100.06	92.02	84.99
4.0%	127.78	115.73	105.45	96.58	88.88

Source: Company data, CMBIS estimates

Investment risks

The Company's financial prospects depend substantially on the success of its product portfolio

Airdoc's business substantially depends on the successful development, regulatory approval and commercialization of the products in its existing product portfolio and other products the Company may develop in the future. Airdoc has invested a significant portion of its efforts and financial resources in the development of the existing product portfolio. The Company has incurred significant expenses related to the research and development of its pipeline products in the past. As a result, the Company recorded net losses of RMB87.1mn, RMB79.6mn, RMB25.3mn and RMB12.1mn for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2020 and 2021, respectively. The Company's research and development expenses amounted to 135.5%, 88.8%, 399.9% and 49.7% of its total revenue for the same periods, respectively.

The Company has relatively limited experience in marketing and sales of its Core Product

Airdoc received the Class III medical device registration certificate from the NMPA for Airdoc-AIFUNDUS (1.0) in August 2020 and began to implement its commercialization strategy since then. As of June 13, 2021, the Company has marketed and provided Airdoc-AIFUNDUS (1.0) to two hospitals in China and have generated limited revenue. Airdoc is still in the early stage of commercialization of its Airdoc-AIFUNDUS (1.0). As such, the Company has relatively limited experience in launching and commercializing its Core Product. In particular, Airdoc has limited experience in building a sales and marketing team, conducting a comprehensive marketing analysis, and obtaining licenses and approvals necessary for market penetration. As a result, Airdoc's ability to successfully commercialize its pipeline products may involve more inherent risks.

In addition, there may be circumstances during the actual sales of Airdoc's future products that it did not anticipate prior to commercialization that may require the Company to adjust its sales and marketing strategies, recruit additional personnel or incur unforeseen costs and expenses to address those circumstances. In such event, the business prospects and sales of relevant products could be materially and adversely affected.

Reliance on a limited number of major customers

For the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, the aggregated sales to Airdoc's five largest customers were RMB25.6mn, RMB40.8mn and RMB18.9mn, respectively, accounting for 84.1%, 85.5% and 85.2% of its total revenue for the respective periods. Sales to the largest customer for the same period amounted to RMB13.2mn, RMB20.8mn and RMB9.0mn, respectively, representing 43.5%, 43.5% and 40.6% of the Company's total revenue for the same period, respectively. As such, Airdoc may be subject to concentration and counter-party risks from these customers. There can be no assurance that these major customers will continue their purchases, if at all, from Airdoc at the current levels. In addition, there is no assurance that the Company will be able to maintain strong relationships with these customers, or that these customers will continue to work with Airdoc or renew their agreements with it on similar or commercially reasonable terms in the future. Moreover, the Company cannot guarantee that its major customers will not have a change in business scope or business model, will not cease to operate, will operate in compliance with applicable laws, will be able to maintain their appropriate licenses and approvals for their operations or will not experience operational or financial difficulties. Any material adverse change to the business, operations and financial condition of these customers may have a significant adverse

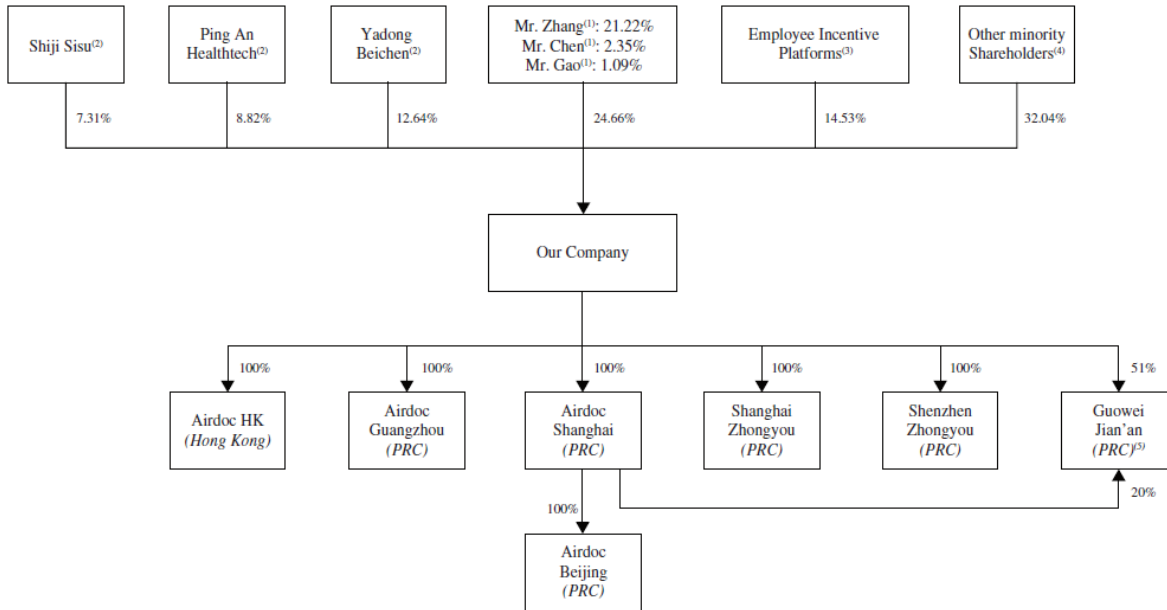
impact on the Company, and if it is unable to find new customers on comparable commercial terms within a reasonable period of time, the business, financial condition and results of operations may be adversely affected.

Supply reliance on third-party OEM

Airdoc engaged OEM service providers to manufacture its own hardware devices. Pursuant to the Company's agreements with these OEM service providers, they are responsible for assembling and ensuring the compliance with regulatory standards. Selecting, managing and supervising these third-party OEM service providers and raw materials suppliers requires significant resources and expertise. Any disruption in production or inability of the Company's OEM service providers and raw materials suppliers to produce adequate quantities to meet the needs could impair Airdoc's ability to manufacture products as scheduled and to operate business on a day-to-day basis. Moreover, Airdoc expects its demand for such OEM services and raw materials to increase as the Company expands its business scale and commercialize the products, and Airdoc cannot guarantee that current suppliers have the capacity to meet its demand. The Company is also exposed to the possibility of increased OEM service fees or raw material costs, which it may not be able to pass on to customers, and as a result, lower the Company's profitability. In addition, although Airdoc has implemented quality inspection procedures on the services and raw materials it procures and require the OEM service providers and raw materials suppliers to maintain high quality standards, the Company cannot guarantee that it will be able to detect all quality issues in the supplies and services. These third parties may not be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the services or raw materials supplied to the Company. If they are unable to do so and the quality of the Company's products suffers as a result, Airdoc may have to delay provision of hardware devices, recall its products, be subject to product liability claims, fail to comply with continuing regulatory requirements and incur significant costs to rectify such issue, which may have a material and adverse effect on the Company's business, financial condition and results of operations.

Appendix: Company profile

Figure 25: Shareholder structure (Pre-IPO)



Source: PHIP, CMBIS

Figure 26: Management profile

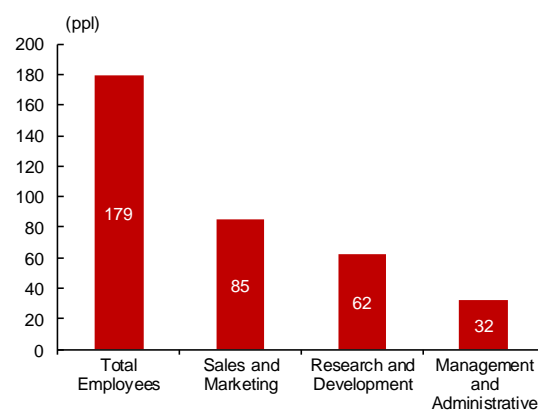
Name	Age	Date of Joining	Position	Roles and Responsibilities
Dalei ZHANG (张 大 磊)	38	2015/09/09	Executive Director, chairman of the Board, and chief executive officer	Responsible for the overall management of the business strategy and corporate development of the Group
Fei GAO (高 斐)	38	2015/09/09	Executive Director	Responsible for the management of investor relationship, legal matters and optometry related business of the Group
Yuzhong CHEN (陈 羽 中)	49	2018/11/30	Executive Director	Responsible for medical R&D, product registration and overall operational support of the Group
Hailong CHEN (陈 海 龙)	39	2016/08/22	Executive Director	Responsible for design of product structure, R&D and management of R&D team of the Group

Source: PHIP, CMBIS

Figure 27: Employee structure

Function	# of staff	% of Total
Sales and Marketing	85	47.5%
Research and Development	62	34.6%
Management and Administrative	32	17.9%
Total	179	100.0%

Source: PHIP (as of 13 June 2021)

Figure 28: Employee number breakdown

Source: PHIP (as of 13 June 2021)

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