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

FORM 20-F/A
(Amendment No. 3)

(Mark One)
☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from _____ to _____

OR

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

Date of event requiring this shell company report:

Commission file number: **001-41291**

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES CO., LTD.
(Exact Name of Registrant as Specified in Its Charter)

Not Applicable
(Translation of Registrant's Name Into English)

Cayman Islands
(Jurisdiction of Incorporation or Organization)

88 Tongda Road, Touqiao Town
Guangling District, Yangzhou, 225000
People's Republic of China
(Address of Principal Executive Offices)

Xin Wang, Chief Executive Officer
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Guangling District, Yangzhou, 225000
People's Republic of China
Tel: +86-0514-89800199
secretary@meihuamed.com
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange On Which Registered
Ordinary Share, $0.0005 par value	MHUA	Nasdaq Global Market

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

None
(Title of Class)

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

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report (December 31, 2022): 23,940,000

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes ☒ No ☐

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

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

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒	International Financial Reporting Standards as issued by the International Accounting Standards Board ☐	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

EXPLANATORY NOTE

We are filing this Amendment No. 3 to our Annual Report on Form 20-F for the fiscal year ended December 31, 2022, as originally filed with the U.S. Securities and Exchange Commission (the "SEC") on April 14, 2023 (the "Original Annual Report"), and as amended on July 3, 2023 and August 21, 2023 (the "Amendments"), solely for the purpose of updating certain risk factors in response to SEC comments.

Other than as set forth above, and as amended by the Amendments, this Form 20-F/A does not, and does not purport to, amend, update or restate the information in any other item of the Original Annual Report as originally filed with the SEC. As a result, this Form 20-F/A does not reflect any events that may have occurred after the Original Annual Report was filed on April 14, 2023.

Annual Report on Form 20-F
Year Ended December 31, 2022

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INTRODUCTORY NOTES

Use of Certain Defined Terms

Except as otherwise indicated by the context and for the purposes of this report only, references in this report to:

- "China" or the "PRC" refers to the People's Republic of China, including the special administrative regions of Hong Kong and Macau, and only when this report refers to specific laws and regulations adopted by the PRC and the discretion of China governmental authorities, reference to "China" or the "PRC" excludes Taiwan and the special administrative regions of Hong Kong and Macau;

- Depending on the context, "we," "us," "our company," "our," "the Company," and "Meihua International" refer to Meihua International Medical Technologies Co., Ltd., 美华国际医疗科技有限公司, a Cayman Islands company, its subsidiaries, Kang Fu International Medical Co., Limited ("Kang Fu International Medical"), Yangzhou Huada Medical Device Co., Ltd ("Yangzhou Huada"), Jiangsu Yada Technology Group Co., Ltd. ("Jiangsu Yada"), Jiangsu Huadong Medical Device Industrial Co., Ltd. ("Jiangsu Huadong"), and Yangzhou Guanghui Medical Technology Co., Ltd. ("Guanghui");

- "Kang Fu International Medical" refers to Kang Fu International Medical Co., Limited, a limited company organized under the laws of Hong Kong and a wholly owned subsidiary of Meihua International;

- "Yangzhou Huada" refers to Yangzhou Huada Medical Device Co., Ltd, a limited liability company organized under the laws of China, which is wholly owned by Kang Fu International Medical;

- "Jiangsu Yada" refers to Jiangsu Yada Technology Group Co., Ltd, a limited liability company organized under the laws of China, which is wholly owned by Yangzhou Huada;

- "Jiangsu Huadong" refers to Jiangsu Huadong Medical Device Industrial Co., Ltd, a limited liability company organized under the laws of China and a wholly owned subsidiary of Jiangsu Yada;

- "Guanghui" refers to Yangzhou Guanghui Medical Technology Co., Ltd, a limited liability company organized under the laws of China, which is wholly owned by Jiangsu Huadong.

- "shares," "Shares" or "Ordinary Shares" refer to the Ordinary Shares of Meihua International Medical Technologies Co., Ltd., par value $0.0005 per share;

- "RMB" or "Chinese Yuan" refers to the legal currency of China;

- "U.S. dollars," "dollars," "USD" or "$" refers to the legal currency of the United States;

- "HKD" refers to the official currency of Hong Kong.

- "GMV" refers to the total value of all orders shipped for products sold under our sales model, net of returns;

- "medical professionals" refer to doctors, pharmacists and medical assistants;

- "SKU," refers to stock keeping unit;

- "Websites" refers to our websites at http://meihuamed.com and http://ir.meihuamed.com.

Cautionary Note Regarding Forward-Looking Statements

In addition to historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. We use words such as "believe," "expect," "anticipate," "project," "target," "plan," "optimistic," "intend," "aim," "will" or similar expressions which are intended to identify forward-looking statements. Such statements include, among others, those concerning market and industry segment growth and demand and acceptance of new and existing products; any projections of sales, earnings, revenue, margins or other financial items; any statements of the plans, strategies and objectives of management for future operations; and any statements regarding future economic conditions or performance, as well as all assumptions, expectations, predictions, intentions or beliefs about future events. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, as well as assumptions, which, if they were to ever materialize or prove incorrect, could cause the results of the Company to differ materially from those expressed or implied by such forward-looking statements. Potential risks and uncertainties include, among other things, the possibility that we may not be able to maintain or increase our net revenues and profits due to our failure to anticipate consumer preferences and develop new menswear products, our failure to execute our business expansion plan, changes in domestic and foreign laws, regulations and taxes, changes in economic conditions, uncertainties related to China's legal system and economic, political and social events in China, a general economic downturn, a downturn in the securities markets, and other risks and uncertainties which are generally set forth under "Item 3. Key information—D. Risk Factors" and elsewhere in this report.

Readers are urged to carefully review and consider the various disclosures made by us in this report and our other filings with the SEC. These reports attempt to advise interested parties of the risks and factors that may affect our business, financial condition and results of operations and prospects. The forward-looking statements made in this report speak only as of the date hereof and we disclaim any obligation, except as required by law, to provide updates, revisions or amendments to any forward-looking statements to reflect changes in our expectations or future events.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

Not applicable.

B. Advisors

Not applicable.

C. Auditors

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

A. Offer Statistics

Not applicable.

B. Method and Expected Timetable

Not applicable.

ITEM 3. KEY INFORMATION

In this annual report on Form 20-F (the "Annual Report"), "Meihua," refers to Meihua International Medical Technologies Co., Ltd., 美华国际医疗科技有限公司, a Cayman Islands company, and depending on the context, "we," "us," "our company," "our," "the Company" and "Meihua International" refer to Meihua International Medical Technologies Co., Ltd., 美华国际医疗科技有限公司, a Cayman Islands company, its subsidiaries, Kang Fu International Medical Co., Limited ("Kang Fu International Medical"), Yangzhou Huada Medical Device Co., Ltd. ("Yangzhou Huada"), Jiangsu Yada Technology Group Co., Ltd. ("Jiangsu Yada"), Jiangsu Huadong Medical Device Industrial Co., Ltd. ("Jiangsu Huadong"), and Yangzhou Guanghui Medical Technology Co., Ltd. ("Guanghui").

Our Holding Company Structure

Meihua is a holding company which was incorporated under the laws of Cayman Islands on November 10, 2020 by our shareholder Yongjun Liu. Meihua's direct subsidiary is Kang Fu International Medical, a Hong Kong company. Kang Fu International Medical was incorporated on October 13, 2015 by four shareholders, Yongjun Liu, Yin Liu, Ace Capital Limited and King Tai International Holding Limited. On November 22, 2019, Yongjun Liu acquired 9,300,000 shares in Kang Fu International Medical from Ace Capital Limited and 4,500,000 shares in Kang Fu International Medical from King Tai International Holding Limited, respectively. Upon consummation of such share transfer, Yongjun Liu and Yin Liu constituted all of the shareholders of Kang Fu International Medical, holding 100% shares of Kang Fu International Medical. On December 21, 2020, Meihua in turn acquired 41,400,000 shares (69% of the outstanding shares) from Yongjun Liu and 18,600,000 shares (31% of the outstanding shares) from Yin Liu, respectively, resulting in Kang Fu International Medical becoming Meihua's wholly owned subsidiary. In exchange for the acquisition on Kang Fu, Meihua issued a total of 15,935,000 Ordinary Shares to Mr. and Mrs. Liu, who in turn transferred their shares to Bright Accomplish Limited, a holding company for which they are the sole shareholders, on December 21, 2020. Bright Accomplish Limited is Meihua's controlling shareholder, holding approximately 66.56% of Meihua's Ordinary Shares as of the date of this report.

Meihua is not a Chinese operating company but a Cayman Islands holding company with operations conducted by its subsidiaries located in mainland China. Meihua operates its business through its indirect subsidiaries in China. Below is a list of Meihua's operating subsidiaries:

- Yangzhou Huada Medical Device Co., Ltd., or Yangzhou Huada: a subsidiary wholly owned by Kang Fu International Medical and established in Yangzhou, Jiangsu Province, PRC on December 24, 2001 with a registered capital of $602,400, which manufactures and sells Class I disposable medical devices under our own brands, and distributes Class I and Class II disposable medical devices sourced from other manufacturers, to our domestic customers. Specifically, Yangzhou Huada mainly focuses on the manufacturing, sales and distributions of non-bottled products, such as brushes, ID bracelets for domestic sales.

- Jiangsu Yada Technology Group Co., Ltd., or Jiangsu Yada: a subsidiary wholly owned by Yangzhou Huada and established in Yangzhou, Jiangsu Province, PRC on December 5, 1991 with a registered capital of RMB51,390,000, which manufactures and sells Class I and Class II disposable medical devices under our own brands, and distributes Class I and Class II disposable medical devices sourced from other manufacturers, to our domestic and overseas customers. Specifically, Jiangsu Yada mainly focuses on overseas sales.

- Jiangsu Huadong Medical Device Industrial Co., Ltd., or Jiangsu Huadong: a subsidiary wholly owned by Jiangsu Yada and established in Yangzhou, Jiangsu Province, PRC on November 18, 2000 with a registered capital of RMB50,000,000, which manufactures and sells Class I, II and III disposable medical devices under our own brands, and distributes Class I, II and III disposable medical devices sourced from other manufacturers, to our domestic and overseas customers. Specifically, Jiangsu Huadong mainly focuses on the manufacturing, sales and distributions of polyethylene bottled products, such as eye drop bottles and tablet bottles.

- Yangzhou Guanghui Medical Technology Co., Ltd., or Guanghui: a subsidiary wholly owned by Jiangsu Huadong was established in Yangzhou, China on December 22, 2020 with a registered capital of RMB1,000,000, to mainly manufactures and sells Class II disposable medical devices. Guanghui has not conduct real business.

- Hainan Guoxie Technology Group Co., Ltd., or Hainan Guoxie: a subsidiary of which 55% of registered capital (subscribed but unpaid registered capital) was acquired by Kang Fu International Medical from an individual Qin Wang with nil consideration on July 6, 2022, in order to conduct local business activities in Hainan. Hainan Guoxie was established in Qionghai, Hainan Province, China on October 7, 2021 with a registered capital of RMB100,000,000. Further disclosure will be made in 6-K regarding the new controlling subsidiary.

Meihua owns 100% of Kang Fu International Medical. Kang Fu International Medical owns 100% of Yangzhou Huada and 55% of Hainan Guoxie. Yangzhou Huada owns 100% of Jiangsu Yada. Jiangsu Yada, in turn, owns 100% of Jiangsu Huadong. Jiangsu Huadong, in turn, owns 100% of the equity interests of Guanghui. The following diagram illustrates the Company's corporate structure as of the date of this report, including Meihua's principal subsidiary and their respective principal subsidiaries.

Cash Flows through Our Company

The structure of cash flows within our organization, and a summary of the applicable regulations, is as follows:

1. Our equity structure is a direct holding structure, pursuant to which the overseas entity listed in the U.S., Meihua International Medical Technologies Co., Ltd. ("Meihua" or Meihua International"), directly controls Yangzhou Huada Medical Device Co., Ltd ("Yangzhou Huada") (the "WFOE") and other domestic operating entities which are directly owned through the Hong Kong company, Kang Fu International Medical Co., Limited ("Kang Fu International Medical").

2. Within our direct holding structure, the cross-border transfer of funds within our corporate group is legal and compliant with the laws and regulations of the PRC. After foreign investors' funds enter Meihua International at the close of securities offerings, the funds can be directly transferred to Kang Fu International Medical, and then transferred to subordinate operating entities through the WFOE.

If the Company intends to distribute dividends, the Company will transfer the dividends to Kang Fu International Medical in accordance with the laws and regulations of the PRC, and then Kang Fu International Medical will transfer the dividends to Meihua International, and the dividends will be distributed from Meihua International to all shareholders respectively in proportion to the shares they hold, regardless of whether the shareholders are U.S. investors or investors in other countries or regions.

3. In the reporting periods presented in this Annual Report, cash and other asset transfers occurred among the Company and its subsidiaries are as summarized as below:

	For the year ended December 31, 2022 (in US$)		
Inter-company cash transfers:	**Meihua (Cayman)**	**Kang Fu International Medical (HK)**	**PRC subsidiaries**
Cash transferred from Meihua to Kang Fu International Medical (1)	$ (26,010,150)	$ 26,010,150	-
Cash transferred from Kang Fu International Medical to Meihua (2)	$ 390	$ (390)	-
Cash transferred from Kang Fu International Medical to PRC subsidiaries (3)	-	$ (20,389,970)	$ 20,389,970
Cash transferred from PRC subsidiaries to Kang Fu International Medical (4)	-	$ 130,000	$ (130,000)

(1) Meihua transferred $26,010,150 to Kang Fu International Medical as a loan to cover working capital.
(2) Kang Fu International Medical transferred $390 to Meihua for repayment of a working capital loan.
(3) Kang Fu International Medical contributed $20,389,970 to PRC subsidiaries for capital contribution purposes.*
(4) Yangzhou Huada, one of the PRC subsidiaries, transferred $130,000 to Kang Fu International Medical as a loan to cover working capital.

* On February 18, 2022, the Company closed its initial public offering of Ordinary Shares and received approximately US$35 million. In March and April 2022, the Company transferred approximately US$26.0 million to Kang Fu International Medical for working capital purposes and then Kang Fu International Medical made capital injections aggregating approximately US$20.4 million to its PRC subsidiaries - Yangzhou Huada and Hainan Guoxie.

	For the year ended December 31, 2021 (in US$)		
Inter-company cash transfers:	**Meihua (Cayman)**	**Kang Fu International Medical (HK)**	**PRC subsidiaries**
Cash transferred from Kang Fu International Medical to PRC subsidiaries (5)	-	$ (46,297)	$ 46,297
Cash transferred from PRC subsidiaries to Kang Fu International Medical (6)	-	$ 768,042	$ (768,042)

(5) KangFu International Medical transferred $46,297 to PRC subsidiaries for repayment of working capital loan.
(6) Yangzhou Huada, one of our PRC subsidiaries, transferred $768,042 to Kang Fu International Medical for working capital loan purposes.

	For the year ended December 31, 2020 (in US$)		
Inter-company cash transfers:	**Meihua (Cayman)**	**Kang Fu International Medical (HK)**	**PRC subsidiaries**
Cash transferred from PRC subsidiaries to Kang Fu International Medical (7)	-	$ 499,998	$ (499,998)

(7) Yangzhou Huada, one of Meiahua's PRC subsidiaries, transferred $499,998 to Kang Fu International Medical for working capital loan purposes.

4. No dividends or distributions of a subsidiary have been made to the Company for the years ended December 31, 2020, 2021 and 2022. For the foreseeable future, the Company intends to use the earnings for research and development, to develop new products and to expand its production capacity. As a result, we do not expect to pay any cash dividends in the near future.

Our PRC subsidiaries' ability to distribute dividends is based upon their distributable earnings. Current PRC regulations permit our PRC subsidiaries to pay dividends to their respective shareholders only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries is required to set aside at least 10% of its after-tax profits each year, if any, to fund a statutory reserve until such reserve reaches 50% of each of their registered capitals. These reserves are not distributable as cash dividends. See "*Regulations Relating to Dividend Distributions*" for more information.

To address persistent capital outflows and the RMB's depreciation against the U.S. dollar in the fourth quarter of 2016, the People's Bank of China and the State Administration of Foreign Exchange, or SAFE, have implemented a series of capital control measures in the subsequent months, including stricter vetting procedures for China-based companies to remit foreign currency for overseas acquisitions, dividend payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls and our PRC subsidiaries' dividends and other distributions may be subject to tightened scrutiny in the future. The PRC government also imposes controls on the conversion of RMB into foreign currencies and the remittance of currencies out of the PRC. Therefore, we may experience difficulties in completing the administrative procedures necessary to obtain and remit foreign currency for the payment of dividends from our profits, if any. Furthermore, if our subsidiaries in the PRC incur debt on their own in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments.

In addition, the Enterprise Income Tax Law and its implementation rules provide that a withholding tax at a rate of 10% will be applicable to dividends payable by Chinese companies to non-PRC-resident enterprises unless reduced under treaties or arrangements between the PRC central government and the governments of other countries or regions where the non-PRC resident enterprises are tax resident. Pursuant to the tax agreement between Mainland China and the Hong Kong Special Administrative Region, the withholding tax rate in respect to the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10%. However, if the relevant tax authorities determine that our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable withholding tax in the future. Accordingly, there is no assurance that the reduced 5% withholding rate will apply to dividends received by our Hong Kong subsidiary from our PRC subsidiaries. This withholding tax will reduce the amount of dividends we may receive from our PRC subsidiaries.

Key Information Related to Doing Business in China

Risks and Uncertainties Related to Doing Business in China

Meihua faces various legal and operational risks and uncertainties as a company which its principal subsidiaries based in and primarily operating in China. Most of Meihua's subsidiaries operations are conducted in the PRC, and are governed by PRC laws, rules, and regulations. Because PRC laws, rules, and regulations are relatively new and quickly evolving, and because of the limited number of published decisions and the non-precedential nature of these decisions, and because the laws, rules and regulations often give the relevant regulator certain discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. The PRC government has the power to exercise significant oversight and discretion over the conduct of our business, and the regulations to which we are subject may change rapidly and with little notice to us or our shareholders. As a result, the application, interpretation, and enforcement of new and existing laws and regulations in the PRC are often uncertain. In addition, these laws and regulations may be interpreted and applied inconsistently by different agencies or authorities, and inconsistently with our current policies and practices.

See "— D. Risk Factors — Risks Related to Doing Business in China — Because all of our operations are in China, our business is subject to the complex and rapidly evolving laws and regulations there. The Chinese government may exercise significant oversight and discretion over the conduct of our business and may intervene in or influence our operations at any time, which could result in a material change in our operations and/or the value of our Ordinary Shares." And "— PRC's economic, political and social conditions, as well as changes in any government policies, laws and regulations, could have a material adverse effect on our business."

The PRC government has significant oversight and discretion over the conduct of our business, and may intervene in or influence our operations through adopting and enforcing rules and regulatory requirements. For example, in recent years the PRC government, has enhanced regulation in areas such as anti-monopoly, anti-unfair competition, cybersecurity and data privacy. See "— D. Risk Factors — Risks Related to Our Business and Industry — If the Chinese government chooses to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers, such action could significantly limit or completely hinder our ability to offer or continue to offer securities to investors outside of China and, as a result, cause the value of such securities to significantly decline or be worthless."; and "— Uncertainties with respect to the PRC legal system could adversely affect us."

In addition, our Ordinary Shares may be delisted from Nasdaq or prohibited from being traded over-the-counter under the Holding Foreign Companies Accountable Act if the PCAOB is unable to inspect our auditor for two consecutive years. Our auditor has been inspected by the PCAOB on a regular basis and it is not subject to the determinations announced by the PCAOB on December 16, 2021. If trading in our Ordinary Shares is prohibited under the Holding Foreign Companies Accountable Act in the future because the PCAOB determines that it cannot inspect or fully investigate our auditor at such future time, the Nasdaq Stock Market may determine to delist our Ordinary Shares. On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act and on December 29, 2022, a legislation entitled "Consolidated Appropriations Act, 2023" (the "Consolidated Appropriations Act") was signed into law by President Biden, which contained, among other things, an identical provision to Accelerating Holding Foreign Companies Accountable Act and reduces the number of consecutive non-inspection years required for triggering the listing and trading prohibitions from three years to two years,, thus reducing the time period before our securities may be prohibited from trading or delisted. On December 15, 2022, the PCAOB Board determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and voted to vacate its previous determinations to the contrary. However, should PRC authorities obstruct or otherwise fail to facilitate the PCAOB's access in the future, the PCAOB Board will consider the need to issue a new determination. Our securities may be delisted or prohibited from trading if the PCAOB determines that it cannot inspect or investigate completely our auditor under the Holding Foreign Companies Accountable Act. Our auditor, Kreit & Chiu CPA LLP, is headquartered in New York, NY with its office at 733 Third Avenue, Floor 16, #1014, New York, NY 10017, and has been inspected by the PCAOB on a regular basis. See "— D. Risk Factors — Risks Related to Doing Business in China — Although the audit report included in this report was issued by U.S. au$itors who are currently inspected by the PCAOB, if it is later determined that the PCAOB is unable to inspect or investigate our auditor completely, investors would be deprived of the benefits of such inspection and our Ordinary Shares may be delisted or prohibited from trading."

Permissions and Approvals Required to be Obtained from PRC Authorities for our Business Operations

As a medical device manufacturing and sales company, we are subject to extensive government regulation and supervision in the PRC. Pursuant to PRC laws, we must obtain production license for Class II and III disposable medical devices and production filing for Class I disposable medical device, operation license for Class III disposable medical devices and operation filing for Class II disposable medical devices, and filing or registration certificates for certain Class I, II or Class III disposable medical devices. As of the date of this Annual Report, we are current on all licenses and certificates and have obtained Class I, II and III disposable medical device qualifications in the PRC.

However, if we fail to timely renew our medical device licenses or registration certificates, it could adversely affect our reputation, financial conditions and results of operations. See "— D. Risk Factors — Risks Related to Our Business and Industry — If we fail to timely renew our medical device licenses or registration certificates, it could adversely affect our reputation, financial conditions and results of operations."

Permissions and Approvals Required to be Obtained from PRC Authorities for our Securities Offerings

As of the date of this Annual Report, we believe that we and our PRC subsidiaries, (1) are not required to obtain permissions from any PRC authorities to operate or issue our Ordinary Shares to foreign investors, (2) are not subject to permission requirements from the China Securities Regulatory Commission (the "CSRC"), the Cyberspace Administration of China (the "CAC") or any other entity that is required to approve our PRC subsidiaries' operations, and (3) have not received or were denied such permissions by any PRC authorities. Nevertheless, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the "Opinions on Severely Cracking Down on Illegal Securities Activities According to Law," or the Opinions, which were made available to the public on July 6, 2021. The Opinions emphasized the need to strengthen the administration over illegal securities activities, and the need to strengthen the supervision over overseas listings by Chinese companies. Given the current PRC regulatory environment, it is uncertain when and whether we or our PRC subsidiaries, will be required to obtain permission from the PRC government to continue to list on U.S. exchanges in the future, and even when such permission is obtained, whether it will be denied or rescinded. We have been closely monitoring regulatory developments in China regarding any necessary approvals from the CSRC or other PRC governmental authorities required for overseas listings. As of the date of this report, we have not received any inquiry, notice, warning, sanctions or regulatory objection to this offering from the CSRC or other PRC governmental authorities. However, there remains significant uncertainty as to the enactment, interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities.

On February 17, 2023, the CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and relevant five supporting guidelines, together as the New Overseas Listing Rules, which became effective on March 31, 2023. According to the New Overseas Listing Rules, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to complete the filing procedure with the CSRC and report relevant information. In addition, an overseas-listed company must also submit the filing with respect to its follow-on offerings, issuance of convertible corporate bonds and exchangeable bonds, and other equivalent offering activities, within the time frame specified by the Trial Measures. The New Overseas Listing Rules laid out the regulatory filing requirements for both direct and indirect overseas listings and clarify the determination criteria for indirect overseas listing in overseas markets. For more detailed information, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Potential Chinese governmental and regulatory interference could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless." Pursuant to the New Overseas Listing Rules, (i) in connection with our previous issuance of securities to foreign investors, neither we, nor our PRC subsidiaries are required to obtain any permissions or approvals from the CSRC, and (ii) should we decide to issue additional equity or equity-linked securities for listing overseas in the future, we are not required to obtain any permissions or approvals from any PRC government authorities, except for the requisite filing with the CSRC in connection with such issuance. Failure to comply with the filing requirements may result in an order of rectification, a warning and fines up to RMB10 million to the non-compliant domestic companies, and the directly responsible persons of the companies will be warned and fined between RMB500,000 and RMB5 million. Furthermore, if the controlling shareholder and the actual controller of the non-compliant companies organizes or instigates the breach, they will be fined between RMB1 million and RMB10 million. In addition to above filing requirements, the Filings Rules also requires an issuer to report to the CSRC within three business days after occurrence of any the following events: (i) its change of control; (ii) its being subject to investigation or sanctions by any overseas securities regulators or overseas authorities; (iii) its change of listing status or listing segment; (iv) voluntary or mandatory delisting; and (v) material change of its principal business operations to the extent that it ceases to be subject to the filing requirements of the Trial Measures.

Enforceability of Civil Liabilities

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability. We incorporated in the Cayman Islands because of certain benefits associated with being a Cayman Islands exempted company, such as political and economic stability, an effective judicial system, a favorable tax system, the absence of foreign exchange control or currency restrictions and the availability of professional and support services. However, the Cayman Islands has a less exhaustive body of securities laws than the United States and provides less protection for investors. In addition, Cayman Islands companies may not have standing to sue before the federal courts of the United States.

Substantially all of our assets are located in the PRC. In addition, all of our directors and officers are nationals or residents of the PRC and all or a substantial portion of their assets are located in the PRC. As a result, it may be difficult for investors to effect service of process within the United States upon us or these persons, or to enforce judgments obtained in U.S. courts against us or them, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States. It may also be difficult for investors to enforce judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors.

Ogier, our counsel as to Cayman Islands law, has advised us that it is uncertain whether the courts of the Cayman Islands will allow shareholders of our company to originate actions in the Cayman Islands based upon securities laws of the United States. In addition, there is uncertainty with regard to Cayman Islands law related to whether a judgment obtained from the U.S. courts under civil liability provisions of U.S. securities laws will be determined by the courts of the Cayman Islands as penal or punitive in nature. If such a determination is made, the courts of the Cayman Islands will not recognize or enforce the judgment against a Cayman Islands company, such as our company. As the courts of the Cayman Islands have yet to rule on making such a determination in relation to judgments obtained from U.S. courts under civil liability provisions of U.S. securities laws, it is uncertain whether such judgments would be enforceable in the Cayman Islands. We have been further advised that there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, although the courts of the Cayman Islands will in certain circumstances recognize and enforce a foreign judgment without any re-examination or re-litigation of the matters adjudicated upon, provided such judgment:

(a) is given by a foreign court of competent jurisdiction;

(b) imposes on the judgment debtor a liability to pay a liquidated sum for which the judgment has been given;

(c) is final;

(d) is not in respect of taxes, a fine or a penalty; and

(e) was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

Subject to the above limitations, in appropriate circumstances, a Cayman Islands court may give effect in the Cayman Islands to other kinds of final foreign judgments such as declaratory orders, orders for performance of contracts and injunctions.

JunHe LLP, our counsel as to PRC law, has advised us that there is uncertainty as to whether PRC courts would (i) recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States, or (ii) entertain original actions brought in each respective jurisdiction against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

JunHe LLP has further advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country or region where the judgment is made or on reciprocity between jurisdictions. China does not have any treaties or other form of reciprocity with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in the PRC will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC law or national sovereignty, security or public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States or in the Cayman Islands.

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

An investment in our capital stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Annual Report, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. In that case, the trading price of our Ordinary Shares could decline, and you may lose all or part of your investment.

In addition, all the operational risks associated with being based in and having operations in mainland China as discussed in this "Item 3. Key Information—D. Risk Factors—Risks Related to Our Business and Industry" also apply to operations in the special administrative regions of Hong Kong and Macau. With respect to the legal risks associated with being based in and having operations in mainland China as discussed in risk factors under "Item 3. Key Information—D. Risk Factors—Risks Related to Our Corporate Structure" and "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China," the laws, regulations and discretion of mainland China governmental authorities discussed in this Annual Report are expected to apply to mainland China entities and businesses only, rather than entities or businesses in the Hong Kong Special Administrative Region or Macau which operate under a different set of laws from mainland China.

Risks Related to Our Business and Industry

In connection with the initial public offering of our Ordinary Shares in February 2022, we entered into certain agreements with a Hong Kong entity pursuant to which we believe we were defrauded of in excess of $10 million; because we failed to disclose such agreements at the time of the initial public offering, regardless of the arguably fraudulent nature of such agreements, we may be subject to potential liabilities or litigation exposure as a result of such agreements.

The Company closed its initial public offering (the "IPO") of its ordinary shares (the "Ordinary Shares") on February 18, 2022, through which the Company raised $39.4 million through the sale of 3,940,000 Ordinary Shares at a purchase price of $10.00 per share. During the roadshow leading up to the IPO, a Hong Kong investment company named Tai He International Group Limited ("Tai He") was referred to the Company by Shengang Securities Company Limited ("Shengang"), the Company's co-underwriter based in the People's Republic of China ("PRC"). Tai He, through negotiations with Shengang, asserted that it would participate in the IPO as an investor. As a development stage PRC medical device company, the Company's management had no experience in the U.S. capital markets and relied on its investment bankers and underwriters in providing guidance and advice concerning its U.S. public offering. Accordingly, the Company was unaware of the actual motives of Tai He. Based on the Company's trust in Shengang and given the circumstances that the Company was unable to make further verification, the Company hastily entered into a series of agreements with Tai He (the "Tai He Agreements").

Pursuant to the Tai He Agreements, Tai He agreed to invest a minimum of $35 million in the IPO subject to the Company making a $7.0 million refundable deposit (the "Refundable Deposit") and advancing a $3.0 million service fee for investor relations and other services (together, the "Services") payable to Tai He. The Company, its affiliates and individual shareholders paid the $7.0 million Refundable Deposit and $3.0 million service fee to Tai He in several installments from January 27, 2022 to March 11, 2022. After March 11, 2022, the Company has made no other payments to, nor had any direct interaction with, Tai He, and, in actuality, the Company never directly communicated with Tai He during the negotiations, only communicating about Tai He and the Tai He Agreements through Shengang.

After the IPO, through the Company's internal risk control process, the Company learned that Tai He does not appear to be an investor in the Company and, when the Company attempted to inquire about it, Tai He refused to speak with the Company. Based on the facts as investigated and understood by the Company, the Company believes that it was defrauded by Tai He and that Tai He never actually invested $35 million in the IPO. In fact, the Company learned that Tai He made no investments in the Company at all, and Tai He has no involvement in the Company's IPO matters. In addition, the Refundable Deposit has not been repaid to the Company and no Services have been provided to the Company by Tai He. As a result, the Company believes that the Tai He Agreements may be deemed a fraud perpetrated by Tai He and Shengang against the Company by Tai He taking advantage of asymmetric information, including the Company's lack of knowledge and understanding of the U.S. markets, IPO rules and processes, and the trust of the Company.

After consultation with professionals, the Company is now aware that the Tai He Agreements were required to be disclosed to the public and the Company believes that the agreements themselves are fraudulent and non-enforceable, and therefore the Company is disclosing the Tai He Agreements to meet the compliance requirements of the Securities and Exchange Commission ("SEC"). Further, the Company acknowledges that it had improperly relied on the advice, direction and counsel of Shengang when entering into the Tai He Agreements. The Company is now proactively working to terminate the Tai He Agreements and recover the monies already paid to Tai He by the Company. Due to the uncertainty of collection, the Company has written off approximately $4.8 million deposit and fully expensed $2.3 million service fee paid by the Company to Tai He in the year ended December 31, 2022. The Company and its executive management team intends to cooperate with the SEC, as well as any other relevant authorities, to ensure that its investors' interests are protected while such matters are resolved. Nonetheless, the existence of the Tai He Agreements and the Company's failure to disclose them could expose the Company potential shareholder litigation and/or SEC enforcement or other regulatory action.

Our operating history may not be indicative of our future growth or financial results and we may not be able to sustain our historical growth rates.

Our operating history may not be indicative of our future growth or financial results. There is no assurance that we will be able to grow our revenues in future periods. Our growth rates may decline for any number of possible reasons, and some of them are beyond our control, including decreasing customer demand, increasing competition, declining growth of the medical device industry in general, emergence of alternative business models, or changes in government policies or general economic conditions. We will continue to expand our sales network and product offerings to bring greater convenience to our customers and to increase our customer base and number of transactions. However, the execution of our expansion plan is subject to uncertainty and the total number of items sold and number of transacting customers may not grow at the rate we expect for the reasons stated above. If our growth rates decline, investors' perceptions of our business and prospects may be adversely affected and the market price of our Ordinary Shares could decline.

Failure to maintain the quality and safety of our products could have a material and adverse effect on our reputation, financial condition and results of operations.

The quality and safety of our products, whether self-manufactured or outsourced, are critical to our success. As a medical device manufacturer with a history of over 30 years, and a management team with more than 40 years of industry experience, quality and safety are maintained as our core value. Our medical devices are directly used on the human body and are essential to human health. We pay close attention to quality control, monitoring each step in the process from procurement to production and from warehouse to delivery. Maintaining consistent product quality depends significantly on the effectiveness of our quality control system, which in turn depends on a number of factors, including but not limited to the design of our quality control system, employee training to ensure that our employees adhere to and implement our quality control policies and procedures and the effectiveness of monitoring of any potential violation(s) of our quality control policies and procedures. There can be no assurance that our quality control system will always prove to be effective.

In addition, the quality of the products or services provided by our suppliers or business partners is subject to factors beyond our control, including the effectiveness and the efficiency of their quality control system, among others. There can be no assurance that our suppliers or business partners will always be able to adopt appropriate quality control systems and meet our stringent quality control requirements in respect of the products or services they provide. Any failure of our suppliers or business partners to provide satisfactory products or services could harm our reputation and adversely impact our operations. In addition, we may be unable to receive sufficient compensation from suppliers and business partners for the losses caused by them.

As of the date of this report, we are unaware of any material accidents related to the quality or safety of our products.

Any failure to maintain effective quality control over our products and services could materially adversely affect our business.

The quality of our services and products is critical to the success of our business, and such quality to a large extent depends on the effectiveness of our quality control system. We have developed a rigorous quality control system that enables us to monitor each stage of the production process.

However, despite our quality control management system, we cannot eliminate all risks of errors, defects or failures. We may fail to detect or cure defects as a result of a number of factors, many of which are outside our control, including:

- technical or mechanical malfunctions in the production process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- defective raw materials or equipment.

Failure to detect quality defects in our products could result in patient injury, customer dissatisfaction, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenue and profitability.

In 2018, our PRC subsidiaries Jiangsu Yada and Jiangsu Huadong were fined an immaterial amount for noncompliance with certain local laws and regulations, which non-compliance was cured by us in the same year.

For the fiscal year of 2022 and as of the date of report, we are not aware of any material investigations, prosecutions, disputes, claims or other proceedings relating to quality or quality control issues, nor has the Company received any notices of, been punished for, nor can we foresee any punishment being made by any related government authorities of the PRC as of the date of this report.

Due to the nature of our business, we may experience or be exposed to significant liability claims or complaints from customers, doctors, patients or hospitals, litigation and regulatory investigations and proceedings, such as claims arising in relation to medical device safety, or adverse publicity involving our products, which could adversely affect our financial condition and results of operations.

We face an inherent risk of liability claims or complaints related to the use of our products by our customers, doctors, patients and hospitals. We take those complaints and claims seriously and endeavor to reduce such complaints by implementing various remedial measures. Nevertheless, we cannot assure you that we can successfully prevent or address all such complaints.

Any complaints or claims against us, even if meritless and unsuccessful, may divert management's attention and other resources from our business and adversely affect our business and operations. Such complaints or claims may cause customers to lose confidence in us and our brand, which may adversely affect our business and results of operations. Furthermore, negative publicity including but not limited to negative online reviews on social media and crowd-sourced review platforms, industry findings or media reports related to medical device quality and safety, public health concerns, illness, injuries, whether or not accurate, and whether or not concerning our products, can adversely affect our business, results of operations and reputation.

We face potential liability, expenses for legal claims and exposure to other harm due to the nature of our business. For example, customers could assert legal claims against us in connection with personal injuries or illness related to the use of medical devices we sell. The PRC government, media outlets and public advocacy groups have been increasingly focused on customer protection in recent years. Selling of defective products may expose us to liabilities associated with customer protection laws. We may be deemed responsible for compensating customer losses even if personal injuries or illness are not directly caused by us. Such liability could arise through the actions of our suppliers or business partners. Thus, we may be held liable if our suppliers or other business partners fail to comply with applicable product quality and safety related rules and regulations. In such a situation, though we can ask the responsible parties to indemnify us for such liability, even if we receive full indemnification our reputation could still be adversely affected.

We may face additional exposure to claims and lawsuits. These claims could divert management time and attention away from our business and result in significant costs to investigate and defend, regardless of the merits of the claims. In some instances, we may elect or be forced to pay substantial damages if we are unsuccessful in our efforts to defend against these claims, which could harm our business, financial condition and results of operations. In addition, our directors, management and employees may from time to time be subject to litigation and regulatory investigations and proceedings or otherwise face potential liability and expense in relation to medical device quality and safety, commercial, labor, employment, securities or other matters, which could adversely affect our reputation and results of operations.

As of the date of this report, we are not aware of any notices, warnings, investigations, prosecutions, disputes, claims or other proceedings related to customer rights protection having been brought against us, nor have we been punished or fined or can we foresee any punishment or fines to be made by any government authorities of the PRC or any other jurisdiction.

We face the risk of fluctuations in the cost, availability and quality of our raw materials, which could adversely affect our results of operations.

The cost, availability and quality of our principal raw materials, such as rubber, chemical PE, polyethylene, polypropylene, nylon, non-woven fabrics and other bulk commodities, are important to our operations. After years of development, we have established long-term cooperative relationships with numerous raw material suppliers under a positive price negotiation and adjustment mechanism. However, if the cost of raw materials increases due to policy changes, large market price fluctuations or any other reasons, our business and results of operations could be adversely affected.

Lack of availability of raw materials, whether due to shortages in supply, delays or interruptions in processing, failure of timely deliver materials or otherwise, could interrupt our operations and adversely affect our financial results.

Defective raw materials or raw materials with quality issues could subject us to product liability claims or legal actions, which could adversely affect our financial conditions and results of operations.

A significant interruption in the operations of our third-party suppliers and other business partners could potentially disrupt our operations.

We have limited control over the operations of our third-party suppliers and other business partners and any significant interruption in their operations may have an adverse impact on our operations. For example, a significant interruption in the operations of our supplier's manufacturing facilities could cause delay or termination of shipment of the raw materials to us, which may cause delay or termination of shipment of ordered products to our customers, resulting in damage to our customer relationships. If we could not solve the impact of the interruptions of operations of our third-party suppliers, our business operations and financial results may be materially and adversely affected.

Although we believe that we could establish alternate sources from other suppliers for most of our raw materials, any delay in locating and establishing relationships with other sources could result in shortages or back orders for such raw materials. There can be no assurance that such replacement suppliers will provide the raw materials that are needed by us in the quantities that we request or at the prices that we are willing to pay. Any shortage in quantities or increase in prices could adversely affect our financial conditions and results of operations.

As the relevant land plots are of allocated land use right, we may be required to pay the land granting fees to convert such allocated land use rights to granted land use rights.

Allocated land use rights may only be held by Chinese state-owned enterprises, government authorities and public entities or used for certain prescribed purposes - for example, military installations and infrastructure projects. Allocated lands may be requisitioned by the state at any time and without compensation. An allocated land use right may be converted to a granted land use rights by the payment of land granting fees to the land authority. Therefore, we might be required to convert the land use rights of the relevant land plots from "allocated" to "granted" by payment of the land granting fees.

While we utilize numerous suppliers, we do not have long term contracts with any of those suppliers and they could reduce order quantities or terminate their sales to us at any time.

While we utilize numerous suppliers, we do not have long term contracts with any of those suppliers. As a result, at any time, our suppliers could reduce the quantities of products they sell to us or cease selling products to us altogether. Such reductions or terminations could have a material adverse impact on our revenues, profits and financial condition.

Overall tightening of the labor market, increases in labor costs or any possible labor unrest may adversely affect our business and results of operations.

Our business requires a substantial number of personnel. Any failure to retain and maintain stable and dedicated workforce by us may lead to disruption to our business operations. Although we have not experienced any labor shortages to date, we have observed an overall tightening and increasingly competitive labor market. We have experienced, and expect to continue to experience, increases in labor costs due to increases in salary, social benefits and employee headcount. We compete with other companies in our industry and other labor-intensive industries for labor, and we may not be able to offer competitive remuneration and benefits compared to them. If we are unable to manage and control our labor costs, our business, financial condition and results of operations may be materially and adversely affected.

We are dependent on our top customers. If we fail to acquire new customers or retain existing customers in a cost-effective manner, our business, financial condition and results of operations may be materially and adversely affected.

Maintaining existing customers and developing new customers are always essential to our success. Although we are not heavily dependent on one or two customers, we are still dependent on our top customers. For the years ended December 31, 2022, 2021 and 2020, our top five customers contributed approximately 56.53%, 56.96%, and 53.47%, respectively, to our revenue.

Our ability to cost-effectively attract new customers and retain existing customers, especially our top customers, is crucial to driving net revenues growth and achieving profitability. We have invested significantly in branding, sales and marketing to acquire and retain customers since our inception. For example, we attend domestic and international expos and exhibitions in marketing our products and attracting new customers. We also expect to continue to invest significantly to acquire new customers and retain existing ones, especially our top customers. There can be no assurance that new customers will stay with us, or the net revenues from new customers we acquire will ultimately exceed the cost of acquiring those customers. In addition, if our existing customers, especially our existing top customers no longer find our products appealing, or if our competitors offer more attractive products, prices, discounts or better customer services, our existing customers may lose interest in us, decrease their orders or even stop ordering from us. If we are unable to retain our existing customers, especially our top customers or to acquire new customers in a cost-effective manner, our revenues may decrease and our results of operations will be adversely affected.

If we are unable to build and maintain sufficient sales and distribution network to meet increasing demand of our products, our ability to execute on our business plan as outlined in this report will be impaired.

We sell our products through our direct sales force and distribution channel. As of the date of this report, we have 81 employees in our sales department and 5,000 independent sales agents, 3,004 distributors for domestic sales and 324 exporting distributors for overseas sales. Each of the aforementioned 324 exporting distributors may sell medical devices to at least three overseas customers. We have also established a cooperative network with more than 525 hospitals through our direct sales network. For the years ended December 31, 2022, 2021, and 2020, our direct sales force contributed 9.16%, 9.13%, and 10.59% a, respectively, to our revenues, and distributors contributed 90.84%, 90.87%, and 89.41%, respectively, to our revenues.

Although our sales and distribution satisfy our existing business needs, they might be insufficient to meet demand for our products as we continue to grow our business, which could result in harm to our sales and business operations, financial condition and results of operations. To mitigate such risk, we intent to invest our internally generated cash from operations and capital to be raised to add additional teams to our direct sales force, expand our geographic reach with new distribution channels into other provinces within China and overseas. If our planned efforts to expand our direct sales force and distribution channels are not effective, our ability to execute on our business plan and to realize continued growth with be impaired.

If we fail to provide a one-stop solution to our customers, we may lose customers, which would cause our financial conditions and results of operations to be adversely affected.

We sell our own brand of products and the products of other brands. For the fiscal year ended December 31, 2022, 2021, and 2020, we recognized total revenues of $103,346,341, $104,037,710, and $89,061,010, respectively, of which our own brand sales accounted for 48.88%, 46.19%, and 49.94%, respectively, and the resales of sourced disposable medical devices from other manufacturers accounted for 51.12%, 53.81%, and 50.06%, respectively.

When we receive an order containing products out of our product portfolio, we may procure such products per the specific order requirements from other manufacturers and provide our customers with a one-stop shopping experience. Lack of availability of these products from other manufacturers, whether due to shortages in supply, delays or interruptions in processing, failure of timely delivery or otherwise, could interrupt our operations and adversely affect our financial results.

Our industry is intensely competitive. We may face competition from, and we may be unable to compete successfully against, new entrants and established companies with greater resources.

The medical device industry is intensely competitive and includes thousands of companies both domestically and internationally. As more medical device companies seek to outsource more of the design, prototyping and manufacturing of their products, we will face increasing competitive pressures to grow our business in order to maintain our competitive position and we may encounter competition from, and lose customers to, other companies with design, technological and manufacturing capabilities similar to ours. Some of our potential competitors may have greater name recognition, greater operating revenues, larger customer bases, longer customer relationships and greater financial, technical, personnel and marketing resources than we have. If we are unsuccessful competing with our competitors for our existing and prospective customers' business, our financial conditions and results of operation may be adversely affected.

Furthermore, increased competition may reduce our market share and profitability and require us to increase our sales and marketing efforts and capital commitment in the future, which could negatively affect our results of operations or force us to incur further losses. Although we continually aim to grow our customer base, there is no assurance that we will be able to continue to do so in the future against current or future competitors, and such competitive pressures may have a material adverse effect on our business, financial condition and results of operations.

The continuing development of our products depends upon our maintaining strong working relationships with our customers, distributors and independent sales agents.

The research, development, marketing and sales of our current products and potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with our customers, distributors and independent sales agents. See "*Our Research and Development*" below. We rely on those professionals to provide us with considerable knowledge and experience regarding the research, development, marketing and sales of our products. Distributors and independent sales agents assist us in marketing and sales, as well as collecting customers' feedbacks and advice related to our products. Researchers at hospital and medical institution customers keep us informed of their latest requirements and R&D results. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development, improvement and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete because of future innovations by our competitors or others, which would have a material adverse effect on our business, financial condition and results of operations.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition and results of operations.

If we fail to identify, acquire and develop other products, we may be unable to grow our business.

As a significant part of our growth strategy, we intend to develop and commercialize additional products through our research and development program or by acquiring additional technologies and patents from third parties. The success of this strategy depends upon our ability to identify, select and acquire the technologies and patents on terms that are acceptable to us.

Any patents and technology we identify or acquire may require additional development efforts prior to commercial manufacturing and sale, including approval or clearance by the applicable regulatory authorities. All products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

If we are unable to develop suitable potential products through internal research programs or by obtaining patents or technologies from third parties, it could have a material adverse effect on our business, financial condition and results of operations.

If we are not able to implement our strategies to achieve our business objectives, our business operations and financial performance will be adversely affected.

Our business plan and growth strategy are based on currently prevailing circumstances and the assumption that certain circumstances will or will not occur, as well as the inherent risks and uncertainties involved in various stages of development. However, there is no assurance that we will be successful in implementing our strategies or that our strategies, even if implemented, will lead to the successful achievement of our objectives. If we are not able to successfully implement our strategies, our business operations and financial performance will be adversely affected.

We are dependent upon certain key executives and highly qualified managers and we cannot assure their retention.

Our success depends, in part, upon the continued services of key members of our management team. Our executives' and managers' knowledge of the market, our business and our company represents a key strength of our business, which cannot be easily replicated. The success of our business strategy and our future growth also depends on our ability to attract, train, retain and motivate skilled managerial, sales, administration, development and operating personnel.

Although we have developed a mature production system, a stable and reliable sales network and marketing team, a complete after-sales service system, and a research and development process and team that keeps us abreast of market needs, and also developed complete management systems, including personnel management and welfare systems, raw material procurement and supply systems, warehousing systems, safe production and manufacturing procedures and systems, capital utilization management systems, sales and after-sales service systems, quality assessment, review and inspection systems, labor safety security system, accountability system for violations of laws and disciplines, and a comprehensive information feedback system, which ensure the normal business development of the company, if we loss any of our key personnel, there can be no assurance that our existing personnel will be adequate or qualified to carry out our strategy, or that we will be able to hire or retain experienced, qualified employees to carry out our strategy. The loss of one or more of our key management or operating personnel, or the failure to attract and retain additional key personnel, could have a material adverse effect on our business, financial condition and results of operations.

If we fail to adopt new technologies to evolving customer needs or emerging industry standards, our business may be materially and adversely affected.

To remain competitive, we must continue to stay abreast of the constantly evolving industry trends and enhance and improve our technology accordingly. Our success will depend, in part, on our ability to identify, develop or acquire leading technologies useful in our business. There can be no assurance that we will be able to use new technologies effectively or meet customer's requirements. If we are unable to adapt in a cost-effective and timely manner in response to changing market conditions or customer preferences, whether for technical, legal, financial or other reasons, our business may be materially and adversely affected.

Changes to our payment terms with both customers and suppliers may materially adversely affect our operating cash flows.

We may experience significant pressure from our suppliers to reduce the number of days our accounts payable remain outstanding. At the same time, we may experience pressure from our customers to extend the number of days before paying our accounts receivable. Any failure to manage our accounts payable and accounts receivable may have a material adverse effect on our business, financial condition and results of operations.

If we are unable to collect account receivables from our customers, our results of operations and cash flows could be adversely affected.

Our business depends on our ability to successfully obtain payment from customers of the amounts they owe us for products sold. As of December 31, 2022 and 2021, our accounts receivable balance amounted to $68,945,792 and $67,101,297, respectively. This growth in receivables reflects, in part, our growth in sales. If we are unable to timely collect our accounts receivable on a timely and consistent basis, however, our cash flows and access to operating capital could be adversely affected.

If we fail to manage our inventory effectively, our operations and financial condition may be materially and adversely affected.

If we fail to manage our inventory effectively, we may be subject to a heightened risk of inventory obsolescence, a decline in inventory value, and significant inventory write-downs or write-offs. As of December 31, 2022 and 2021, our inventory balance amounted to $1,122,038 and $1,251,393, respectively.

Economic recessions could have a significant, adverse impact on our business.

Our revenues are generated from sales of medical devices both domestically and internationally and we anticipate that revenues from such sales will continue to represent a substantial portion of our total revenues in the near future. Our sales and earnings can also be affected by changes in the general economy.

The medical device industry historically has experienced cyclical fluctuations in financial results due to economic recession, downturns in business cycles of our customers, interest rate fluctuations, and other economic factors beyond our control. Deterioration in the economic environment subjects our business to various risks, which may have a material and adverse impact on our operating results and cause us to not reach our long-term growth goals. For example, a downturn in the economy could directly affect the discretionary spending power of our customers and in turn, depress the number of orders for our products.

We may be subject to intellectual property infringement claims, which may be expensive to defend and may disrupt our business and operations.

We cannot be certain that our operations or any aspects of our business do not or will not infringe upon or otherwise violate intellectual property rights held by third parties. For instance, our subsidiary, Jiangsu Huadong was historically a third defendant in an intellectual property infringement case, under which certain products purchased by Jiangsu Huadong involved patent infringement. As of the date of this report, such case has been settled and Jiangsu Huadong has permanently stopped purchasing and selling the infringing products and destroyed the products in stock as requested by court's decision. In the future, however, we may be subject to other legal proceedings and claims relating to the intellectual property rights of others. Such future proceedings could also involve existing intellectual property of which we are not aware and on which our products may inadvertently infringe. We cannot assure you that holders of intellectual property purportedly relating to some aspect of our technology or business, if any such holders exist, would not bring such intellectual property claims or enforcement actions against us in China or any other jurisdiction. If we are found to have violated the intellectual property rights of others, we may be subject to liability for our infringement activities or may be prohibited from using such intellectual property going forward, and, in addition, we may incur licensing fees or be forced to develop alternatives of our own. In addition, we may incur significant expenses, and may be forced to divert management's time and other resources from our business and operations to defend against these infringement claims, regardless of their merits. Successful infringement or licensing claims made against us may result in significant monetary liabilities and may materially disrupt our business and operations by restricting or prohibiting our use of the intellectual property in question, and our business, financial position and results of operations could be materially and adversely affected.

Further, the application and interpretation of China's patent laws and the procedures and standards for granting patents in China are still evolving and uncertain, and we cannot assure you that PRC courts or regulatory authorities would agree with our analysis or interpretation concerning their implementation.

We may not be able to prevent others from the unauthorized use of our intellectual property, which could materially harm our business and competitive position.

We rely on a combination of trademark, fair trade practice, patent, copyright and trade secret protection laws in China, as well as confidentiality procedures and contractual provisions, to protect our intellectual property rights. We enter into confidentiality agreements with our employees that include terms identifying all employee-developed intellectual property as service inventions belonging to the Company. In addition, we are carful to remain current in our annual patent fee payments. We regard our trademark, patents, know-how, proprietary technologies, and similar intellectual property as critical to our success. We may become an attractive target to intellectual property attacks in the future with the increasing recognition of our brand. Any of our intellectual property rights could be challenged, invalidated, circumvented or misappropriated, or such intellectual property may not be sufficient to provide us with competitive advantages. In addition, there can be no assurance that (i) all of our intellectual property rights will be adequately protected, or (ii) our intellectual property rights will not be challenged by third parties or found by a judicial authority to be invalid or unenforceable. Intellectual property protection may not be sufficient in China. Confidentiality agreements may be breached by counterparties, and there may not be adequate remedies available to us for any such breach. Accordingly, we may not be able to effectively protect our intellectual property rights or to enforce our contractual rights in China. In addition, policing any unauthorized use of our intellectual property is difficult, time-consuming and costly and the steps we have taken may be inadequate to prevent the misappropriation of our intellectual property. In the event that we must resort to litigation to enforce our intellectual property rights, such litigation could result in substantial costs and a diversion of our managerial and financial resources. We can provide no assurance that we will prevail in such litigation. In addition, our trade secrets may be leaked or otherwise become available to, or be independently discovered by, our competitors. Any failure in protecting or enforcing our intellectual property rights could have a material adverse effect on our business, financial condition and results of operations.

Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing tariffs affecting certain products manufactured in China. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry and customers. Although cross-border business currently contributes a small portion of our business, as we continue to sell our products internationally in the future, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our products and services, impact the competitive position of our products or prevent us from being able to sell products in certain countries. If any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition, results of operations.

We have no business liability or disruption insurance, which could expose us to significant costs and business disruption.

The insurance industry in China is still at an early stage of development, and insurance companies in China currently offer limited business-related insurance products. We do not have any business liability or disruption insurance to cover our operations. We have determined that the costs of insuring for these risks and the difficulties associated with acquiring such insurance on commercially reasonable terms make it impractical for us to have such insurance. Any uninsured risks may result in substantial costs and the diversion of resources, which could adversely affect our results of operations and financial condition.

We may incur liabilities that are not covered by insurance.

While we seek to maintain appropriate levels of insurance, not all claims are insurable and we may experience major incidents of a nature that are not covered by insurance. We maintain accident insurance for some of our high risk employees, such as electricians. We also provide social security insurance including pension, medical insurance, unemployment insurance, maternity insurance, on-the-job injury insurance and housing fund plans through a PRC government-mandated benefit contribution plan for our employees. We do not carry any key-man life insurance, product liability and professional liability insurance. Even if we were to purchase these kinds of insurance, the insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. We have not purchased any property insurance or business interruption insurance. We have determined that the costs of insuring for related risks and the difficulties associated with acquiring such insurance on commercially reasonable terms make it impractical. We consider our insurance coverage to be sufficient for our business operations in China. We maintain an amount of insurance protection that we believe is adequate, but there can be no assurance that such insurance will continue to be available on acceptable terms or that our insurance coverage will be sufficient or effective under all circumstances and against all liabilities to which we may be subject. If we were to incur substantial losses or liabilities due to fire, explosions, floods, other natural disasters or accidents or business interruption, our results of operations could be materially and adversely affected. We could, for example, be subject to substantial claims for damages upon the occurrence of several events within one calendar year. In addition, our insurance costs may increase over time in response to any negative development in our claims history or due to material price increases in the insurance market in general.

Pandemics and epidemics, natural disasters, terrorist activities, political unrest, and other outbreaks could disrupt our delivery and operations, which could materially and adversely affect our business, financial condition, and results of operations.

Global pandemics, epidemics in China or elsewhere in the world, or fear of spread of contagious diseases, such as Ebola virus disease (EVD), coronavirus disease 2019 (COVID-19), Middle East respiratory syndrome (MERS), severe acute respiratory syndrome (SARS), H1N1 flu, H7N9 flu, and avian flu, as well as hurricanes, earthquakes, tsunamis, or other natural disasters could disrupt our business operations, reduce or restrict our supply of products and services, incur significant costs to protect our employees and facilities, or result in regional or global economic distress, which may materially and adversely affect our business, financial condition, and results of operations. Actual or threatened war, terrorist activities, political unrest, civil strife, and other geopolitical uncertainty could have a similar adverse effect on our business, financial condition, and results of operations. Any one or more of these events may impede our production and delivery efforts and adversely affect our sales results, or even for a prolonged period of time, which could materially and adversely affect our business, financial condition, and results of operations.

We are also vulnerable to natural disasters and other calamities. We cannot assure you that we are adequately protected from the effects of fire, floods, typhoons, earthquakes, power loss, telecommunications failures, break-ins, war, riots, terrorist attacks, or similar events. Any of the foregoing events may give rise to interruptions, damage to our property, delays in production, breakdowns, system failures, technology platform failures, or internet failures, which could cause the loss or corruption of data or malfunctions of our manufacturing facility as well as adversely affect our business, financial condition, and results of operations.

Our international sales are subject to a variety of risks that could adversely affect our profitability and operating results.

We sell disposable medical devices internationally. For the fiscal years ended December 31, 2022, 2021, and 2020, our international sales accounted for 0.48%, 14.22%, and 18.10%, respectively, of our revenues. Although we take measures to minimize risks inherent to our international sales, the following risks may have a negative effect on our profitability and operating results, impair the performance of our foreign sales or otherwise disrupt our business:

- fluctuations in the value of currencies could cause exchange rates to change and impact our profitability;
- greater difficulty in collecting accounts receivable and longer payment cycles, which can be more common in our international sales, could adversely impact our operating results over a particular fiscal period; and
- changes in foreign regulations, export duties, taxation and limitations on imports or exports could increase our operational costs, impose fines or restrictions on our ability to carry on our business or expand our international sales.

We are subject to a variety of environmental laws that could be costly for us to comply with, and we could incur liability if we fail to comply with such laws or if we are responsible for releases of contaminants to the environment.

Our operating subsidiaries are all located in PRC. The manufacturing of our products will generate wastewater, exhaust gas, solid waste and equipment noise. Chinese laws impose various environmental controls on the management, handling, generation, manufacturing, transportation, storage, use and disposal of wastewater, exhaust gas, solid waste, equipment noise and other materials used or generated in the manufacturing of our products. If we fail to comply with any present or future environmental laws, we could be subject to fines, corrective action, other liabilities or the suspension of production.

We pay great attention to environmental protection and governance and have formulated a systematic environmental protection management system in the treatment of our wastewater, exhaust gas, solid waste and equipment noise in accordance with national requirements. However, changes in environmental laws may result in costly compliance requirements or otherwise subject us to future liabilities. To the extent these changes affect our customers and require changes to their demand in medical devices, our customers may have a reduced need for our products, and, as a result, our revenue could adversely affect.

In addition, with the implementation of the fund-raising investment project, our pollutant emissions will increase, resulting in the increase of the environmental protection spending and the difficulty of environmental protection management, which could have an adverse effect on our financial conditions and results of operations.

As of the date of this report, the Company is not aware of any investigations, prosecutions, disputes, claims or other proceedings in respect of environmental protection, nor has the Company been punished or can foresee any punishment to be made by any environmental administration authorities of the PRC.

Failure to keep up with the changes in domestic industry policies or standards could have a material and adverse effect on our reputation, financial condition and results of operations.

As a medical device manufacturer, the products we manufacture and sell are closely related to human health, which is subject to strict supervision by relevant Chinese authorities. The related national government authorities have issued a series of regulatory guidelines and industry policies to ensure the healthy development of the industry. In recent years, as China further deepens the reform of its medical and health system, relevant government departments have successively implemented a series of regulations and policies regarding industry standards, bidding, price formation mechanisms, circulation systems and other related fields, which have brought wide and profound impact on the livelihood and development of pharmaceutical companies.

In April 2016, the General Office of the State Council issued the Notice on Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System in 2016, proposing to actively encourage the implementation of the "two-invoice system" in pilot cities for comprehensive reform of public hospitals. In December 2016, the Medical Reform Office of the State Council promulgated the Opinions on the Implementation of the "Two-Invoice System" in Drug Procurement by Public Medical Institutions (for Trial Implementation), which means that the "Two Invoice System" has been officially launched and will be further promoted nationwide. Under the "two-invoice system," invoices are issued once when pharmaceutical products are sold from manufacturers to wholesalers; and then, invoices are issued again when wholesalers resell the products to hospitals. The aim is to shorten circulation links and reduce hospital procurement costs. Under the "two-invoice system," consumable products manufacturers with advantages of brand and economies of scale could increase their coverage of terminals. At the same time, the "two-invoice system" also presents consumable products manufacturers with higher requirements for the construction and optimization of marketing channels. Manufacturers will need to grow their marketing teams, expand sales networks and improve refined service capabilities.

The deepening of the reform of the domestic pharmaceutical industry and the strengthening of supervision may affect our operations and profitability in the domestic market. If we fail to adapt to the profound changes in industry policies in a timely manner, it could materially and adversely affect our business, financial condition and results of operations.

We depend on our professional technology research and development talents and we cannot assure their retention.

Our success partly depends upon the retention of our professional technology research and development talents ("R&D Talents"). As a high-tech enterprise in the medical device industry, we have a professional R&D Talents team comprised of 30 employees as of the date of this report, who have expertise in polymer materials, medicine, molds, and mechanical automation and possess high-level professional technology expertise and profound industry experience. Among those R&D Talents, seven have a bachelor's degree and the other 23 have received an associate degree. There can be no assurance that our existing R&D Talents will be adequate or qualified to carry out our strategy, or that we will be able to hire or retain new R&D Talents to carry out our strategy. The loss of one or more of our R&D Talents, or the failure to attract and retain additional R&D Talents, could have a material adverse effect on our business, financial condition and results of operations.

In addition, if we fail to establish a competitive incentive mechanism in terms of career prospects, salary, benefits and working environment, we may face the risk of instability in the scientific research team, which could adversely affect our long-term development.

Loss of certain procurement bids could have a material and adverse effect on our reputation, financial conditions and results of operations.

According to the Notice of the Ministry of Health on Further Strengthening the Management of Centralized Procurement of Medical Devices (Wei Gui Cai Fa [2007] No. 208), centralized procurement of medical equipment within the large medical equipment management list is required. For other medical equipment and consumables, the provincial health administrative department shall study and formulate a centralized procurement catalog at the provincial and prefecture level based on actual conditions. In recent years, China has actively promoted a provincial-level bidding platform for medical devices with reference to the drug procurement bidding platform. At present, some provinces and cities have conducted a unified bid for some types of medical devices. According to the Notice of the Office of the National Healthcare Security Administration on Centralized Pharmaceutical Purchasing and Price Management in 2023 (Yi Bao Ban Han [2023] No. 13) and the Notice on Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System in 2022 (Guo Ban Fa [2022] No. 14)，it is a strategy to continually promote the volume-based centralized procurement for medical devices in a long-term period.

Under the centralized procurement model, the price information becomes more transparent and open, which will put greater downward pressure on the winning bid price of the product. If we lose a bid to our competitors due to the disadvantage of product price or other reason, we will lose some hospital customers. If the local procurement platform does not solicit a supplementary bid for a long time or reopen the bid, it could have a material and adverse effect on our reputation, financial conditions and results of operations.

If our employees or customers are involved in improper medical device sales transactions, it could adversely affect our reputation, financial conditions and results of operations.

We have established and improved our internal control system against unfair business practices, to prevent, minimize and eliminate employees and customers improper behaviors in the medical device sales transactions, including unauthorized rebates. There can be no assurance that our existing internal control system will be adequate to prevent, minimize and eliminate such improper transactions, that we will be able to effectively implement our internal control polices, or that we will be able to perfect our internal control system to eliminate such improper transactions. If any individual employees or downstream customers have improper business practices in the purchase and sale of medical devices, we may be identified by the relevant regulatory authorities as a violator of relevant laws and regulations and thus included in the blacklist of commercial records, which could adversely affect our reputation, financial conditions and results of operations.

If we fail to timely renew our medical device licenses or registration certificates, it could adversely affect our reputation, financial conditions and results of operations.

As a medical device manufacturer with all of our operating subsidiaries located in PRC, all of our manufacturing and sales activities must comply with relevant Chinese laws and regulations. Pursuant to the Measures for the Administration of Registration of Medical Devices promulgated on June 27, 2014and effective on October 1, 2014, as amended from time to time and currently amended as Measures for the Administration of Registration and Recordation of Medical Devices effective on October 1, 2021, Class I medical devices are subject to recordation administration with Class II and Class III medical devices subject to registration administration. We are in the business of manufacturing and sales of Class I, II and III medical devices. If we fail to timely record or register our medical devices, our financial conditions and results of operations will be adversely affected.

As of the date of this report, we are current in the recording and/or registration of all of our medical devices.

Risks Related to Our Corporate Structure

Our directors and officers currently own an aggregate of 66.56% of the total voting power of our outstanding Ordinary Shares.

Currently, our directors and officers collectively own an aggregate of 66.56% of the total voting power of our outstanding Ordinary Shares. These beneficial owners could have significant influence on determining the outcome of any corporate transaction or other matter submitted to the shareholders for approval, including mergers, consolidations, the election of directors and other significant corporate actions. In cases where their interests are aligned and they vote together, these beneficial owners will also have the power to prevent or cause a change in control. Without the consent of some or all of these shareholders, we may be prevented from entering into transactions that could be beneficial to us or our minority shareholders. The interests of these beneficial owners may differ from the interests of our other shareholders. The concentration in the ownership of our Ordinary Shares may cause a material decline in the value of our Ordinary Shares.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited because we are incorporated under Cayman Islands law.

We are an exempted company incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our amended and restated memorandum and articles of association, the Companies Act (2020 Revision) of the Cayman Islands (the "Companies Act") and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary duties of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, although the courts of the Cayman Islands will in certain circumstances recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

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

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. To the extent we choose to follow home country practice with respect to corporate governance matters, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

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

You may be unable to present proposals before annual general meetings or extraordinary general meetings not called by shareholders.

Cayman Islands law provides shareholders with only limited rights to convene a general meeting and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our articles of association allow our shareholders holding shares representing in aggregate not less than ten percent of our voting share capital in issue, to convene a general meeting of our shareholders, in which case our directors are obliged to call such meeting. Advance notice of at least seven days is required for the convening of our general meetings. A quorum required for a meeting of shareholders consists of at least one shareholder present or by proxy, representing a majority of the paid up voting share capital in the Company.

Recently introduced economic substance legislation of the Cayman Islands may impact the Company or its operations

The Cayman Islands, together with several other non-European Union jurisdictions, have recently introduced legislation aimed at addressing concerns raised by the Council of the European Union as to offshore structures engaged in certain activities which attract profits without real economic activity. Effective January 1, 2019, the International Tax Co-operation (Economic Substance) Act, 2018 (the "Substance Law") and issued Regulations and Guidance Notes came into force in the Cayman Islands introducing certain economic substance requirements for "relevant entities" which are engaged in certain "relevant activities," which in the case of exempted companies incorporated before January 1, 2019, will apply in respect of fiscal years commencing July 1, 2019, onwards. A "relevant entity" includes an exempted company incorporated in the Cayman Islands; however, it does not include an entity that is tax resident outside the Cayman Islands. Accordingly, for so long as the Company is a tax resident outside the Cayman Islands, it is not required to satisfy the economic substance test under the Substance Law. Although it is presently anticipated that the Substance Law will have little material impact on the Company or its operations, as the legislation is new and remains subject to further clarification and interpretation it is not currently possible to ascertain the precise impact of these legislative changes on the Company.

Certain judgments obtained against us by our shareholders may not be enforceable.

We are a Cayman Islands company and substantially all of our assets are located in mainland China. All of our current business operations are conducted in mainland China.

In addition, all of our current officers, including Yongjun Liu, Xin Wang, Lianzhang Zhao, Xiaoming E, Huijuan Zhao and Wenzhang Jia are nationals and residents of the PRC. Substantially all of the assets of these persons are located in the PRC. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the United States in the event that you believe that your rights have been infringed under the U.S. federal securities laws or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and of the PRC may render you unable to enforce a judgment against our assets or the assets of our directors and officers.

Risks Related to Doing Business in China

Because all of our operations are in China, our business is subject to the complex and rapidly evolving laws and regulations there. The Chinese government may exercise significant oversight and discretion over the conduct of our business and may intervene in or influence our operations at any time, which could result in a material change in our operations and/or the value of our Ordinary Shares.

As a business operating in China, we are subject to the laws and regulations of the PRC, which can be complex and evolve rapidly. The PRC government has the power to exercise significant oversight and discretion over the conduct of our business, and the regulations to which we are subject may change rapidly and with little notice to us or our shareholders. As a result, the application, interpretation, and enforcement of new and existing laws and regulations in the PRC are often uncertain. In addition, these laws and regulations may be interpreted and applied inconsistently by different agencies or authorities, and inconsistently with our current policies and practices. New laws, regulations, and other government directives in the PRC may also be costly to comply with, and such compliance or any associated inquiries or investigations or any other government actions may:

- Delay or impede our development,
- Result in negative publicity or increase our operating costs,
- Require significant management time and attention, and
- Subject us to remedies, administrative penalties and even criminal liabilities that may harm our business, including fines assessed for our current or historical operations, or demands or orders that we modify or even cease our business practices.

The promulgation of new laws or regulations, or the new interpretation of existing laws and regulations, in each case that restrict or otherwise unfavorably impact the ability or manner in which we conduct our business and could require us to change certain aspects of our business to ensure compliance, which could decrease demand for our products, reduce revenues, increase costs, require us to obtain more licenses, permits, approvals or certificates, or subject us to additional liabilities. To the extent any new or more stringent measures are required to be implemented, our business, financial condition and results of operations could be adversely affected as well as materially decrease the value of our Ordinary Shares.

If the Chinese government chooses to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers, such action could significantly limit or completely hinder our ability to offer or continue to offer securities to investors outside of China and, as a result, cause the value of such securities to significantly decline or be worthless.

Recent statements by the Chinese government have indicated an intent to exert more oversight and control over offerings that are conducted outside of China and/or foreign investments in China based issuers. The PRC has recently promulgated new rules that require companies collecting or holding large amounts of data to undergo a cybersecurity review prior to listing in foreign countries, a move that will significantly tighten oversight over China-based internet giants. The Measures for Cybersecurity Review (2021 version) was promulgated on December 28, 2021 and became effective on February 15, 2022. These measures specify that any “online platform operators” controlling the personal information of more than one million users which seek to list on a foreign stock exchange are subject to prior cybersecurity review.

As our business belongs to the medical instrument industry in China, and our business does not involve the collection of user data or involve any other type of restricted industry, our business is generally outside the scope of the Measures for Cybersecurity Review. Based on the advice of counsel and our understanding of currently applicable PRC laws and regulations, our recent registered initial public offering in the U.S. was not subject to the review or prior approval of the CAC or the CSRC. Uncertainties still exist, however, due to the possibility that laws, regulations or policies in the PRC could change or rapidly evolve in the future. Any future action by the PRC government expanding the categories of industries and companies whose foreign securities offerings are subject to review by the CSRC or the CAC could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and could cause the value of such securities to significantly decline or be worthless.

Potential Chinese governmental and regulatory interference could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

On July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the "Opinions on Severely Cracking Down on Illegal Securities Activities According to Law," or the Opinions. The Opinions emphasized the need to strengthen the administration over illegal securities activities, and the need to strengthen the supervision over overseas listings by Chinese companies. Effective measures, such as promoting the construction of relevant regulatory systems will be taken to deal with the risks and incidents of China-concept overseas listed companies, and cybersecurity and data privacy protection requirements and similar matters.

In addition, an overseas offering and listing is prohibited under any of the following circumstances: (1) if the intended securities offering and listing is specifically prohibited by national laws and regulations and relevant provisions; (2) if the intended securities offering and listing may constitute a threat to or endangers national security as reviewed and determined by competent authorities under the State Council in accordance with law; (3) if there are material ownership disputes over the equity, major assets, and core technology, etc. of the issuer; (4) if, in the past three years, the domestic enterprise or its controlling shareholders or actual controllers have committed corruption, bribery, embezzlement, misappropriation of property, or other criminal offenses disruptive to the order of the socialist market economy, or are currently under judicial investigation for suspicion of criminal offenses, or are under investigation for suspicion of major violations; (5) if, in past three years, directors, supervisors, or senior executives have been subject to administrative punishments for severe violations, or are currently under judicial investigation for suspicion of criminal offenses, or are under investigation for suspicion of major violations; (6) other circumstances as prescribed by the State Council. The Administration Provisions defines the legal liabilities of breaches such as failure in fulfilling filing obligations or fraudulent filing conducts, imposing a fine between RMB 1 million and RMB 10 million, and in cases of severe violations, a parallel order to suspend relevant business or halt operation for rectification, revoke relevant business permits or operational license.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines, which came into effect on March 31, 2023. The Trial Measures and its supporting guidelines reiterate the basic principles of the Draft Rules Regarding Overseas Listing and impose substantially the same requirements for the overseas securities offering and listing by domestic enterprises. Pursuant to the Trial Measures, domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete the filing procedures with the CSRC pursuant to the requirements of the Trial Measures within three working days following its submission of initial public offerings or listing application, or its completion of follow-on offering in the same overseas market where it has listed (including issuance of any corporate convertible bonds, exchangeable bonds and other equity-linked securities, but excluding the offering for employees incentive, dividend distribution by shares and share split). If a domestic company fails to complete the required filing procedures or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as orders to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

According to the Notice on the Administrative Arrangements for the Filing of the Overseas Securities Offering and Listing by Domestic Companies from the CSRC, or the CSRC Notice, which was promulgated on February 17, 2023 and became effective on the same day, the domestic companies that have already been listed overseas before the effective date of the Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers (the "Existing Issuers"). Existing Issuers are not required to complete the filing procedures immediately, and they shall be required to file with the CSRC for any subsequent offerings. Further, according to the CSRC Notice, domestic companies obtained approval from overseas regulatory authorities or securities exchanges (for example, the effectiveness of a registration statement for offering and listing in the U.S. has been approved) for their indirect overseas offering and listing prior to March 31, 2023 but have not yet completed their indirect overseas issuance and listing, are granted a six-month transition period from March 31, 2023 to September 30, 2023. Those issuers that complete their indirect overseas offering and listing within such six-month period are deemed as Existing Issuers and are not required to file with the CSRC for their indirect overseas offerings and listings. Within such six-month transition period, however, if such domestic companies fail to complete their indirect overseas issuance and listing, they shall complete the filing procedures with the CSRC.

However, since the Trial Measures were newly promulgated, their interpretation, application and enforcement remain unclear. If the filing procedure with the CSRC under the Trial Measures is required for any subsequent offerings, listing or any other capital raising activities, which may subject us to additional compliance requirements in the future, we cannot assure you that we will be able to get the clearance of filing procedures under the Trial Measures on a timely basis, or at all. If we do not complete any required record-filing or if we incorrectly conclude that record-filing is not required or if the CSRC or other regulatory agencies promulgate new rules, explanations or interpretations requiring that we obtain their prior approvals or record-filing for any follow-on offering, we may be unable to obtain such approvals and record-filing which could significantly limit or completely hinder our ability to offer or continue to offer securities to our investors.

Furthermore, the PRC government authorities may strengthen oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers like us. Such actions taken by the PRC government authorities may intervene or influence our operations at any time, which are beyond our control. Therefore, any such action may adversely affect our operations and significantly limit or hinder our ability to offer or continue to offer securities and reduce the value of such securities.

As of the date of this report, we and our PRC subsidiaries have not been involved in any investigations on cybersecurity review initiated by the Cyber Administration of China or related governmental regulatory authorities, and have not received any requirements to obtain permissions from any PRC authorities to issue our Ordinary Shares to foreign investors or were denied such permissions by any PRC authorities. However, given the current PRC regulatory environment, it is uncertain when and whether we or our PRC subsidiaries, will be required to obtain permission from the PRC government to list on U.S. exchanges in the future, and even when such permission is obtained, whether it will be denied or rescinded.

We have been closely monitoring regulatory developments in China regarding any necessary approvals from the CSRC or other PRC governmental authorities required for overseas listings. As of the date of this report, except for the potential uncertainties disclosed above, we have not received any inquiry, notice, warning, sanctions or regulatory objection from the CSRC or other PRC governmental authorities. However, there remains significant uncertainty as to the enactment, interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities.

Changes in China's economic, political or social conditions or government policies could have a material adverse effect on our business and operations.

Substantially all of our assets and operations are located in the PRC. Accordingly, our business, financial condition, results of operations and prospects may be influenced to a significant degree by political, economic and social conditions in the PRC generally. The Chinese economy differs from the economies of most developed countries in many respects, including the level of government involvement, development, growth rate, control of foreign exchange and allocation of resources. Although the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in the PRC is still owned by the government. In addition, the Chinese government continues to play a significant role in regulating industry development by imposing industrial policies. The Chinese government also exercises significant control over the PRC's economic growth through allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

While the Chinese economy has experienced significant growth over past decades, growth has been uneven, both geographically and among various sectors of the economy. Any adverse changes in economic conditions in the PRC, in the policies of the Chinese government or in the laws and regulations in the PRC could have a material adverse effect on the overall economic growth of the PRC. Such developments could adversely affect our business and operating results, lead to a reduction in demand for our services and adversely affect our competitive position. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy but may nonetheless have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations. In addition, in the past the Chinese government has implemented certain measures, including interest rate adjustment, to control the pace of economic growth. These measures may cause decreased economic activity in the PRC, which may adversely affect our business and operating results.

Non-compliance with labor-related laws and regulations of the PRC may have an adverse impact on our financial condition and results of operation.

We have been subject to stricter regulatory requirements in terms of entering into labor contracts with our employees and paying various statutory employee benefits, including pensions, housing fund, medical insurance, work-related injury insurance, unemployment insurance and childbearing insurance to designated government agencies for the benefit of our employees. Pursuant to the PRC Labor Contract Law, or the Labor Contract Law, that became effective in January 2008 and its implementing rules that became effective in September 2008 and was amended in July 2013, employers are subject to stricter requirements in terms of signing labor contracts, minimum wages, paying remuneration, determining the term of employees' probation and unilaterally terminating labor contracts. In the event that we decide to terminate some of our employees or otherwise change our employment or labor practices, the Labor Contract Law and its implementation rules may limit our ability to effect those changes in a desirable or cost-effective manner, which could adversely affect our business and results of operations. We believe our current practice complies with the Labor Contract Law and its amendments. However, the relevant governmental authorities may take a different view and impose fines on us.

As the interpretation and implementation of labor-related laws and regulations are still evolving, we cannot assure you that our employment practice does not and will not violate labor-related laws and regulations in China, which may subject us to labor disputes or government investigations. If we are deemed to have violated relevant labor laws and regulations, we could be required to provide additional compensation to our employees and our business, financial condition and results of operations could be materially and adversely affected.

The PRC's economic, political and social conditions, as well as changes in any government policies, laws and regulations, could have a material adverse effect on our business.

All of our operations are located in the PRC and substantially of our net revenues are derived from customers where the contracting entity is located in the PRC. Accordingly, our business, financial condition, results of operations, prospects and certain transactions we may undertake may be subject, to a significant extent, to economic, political and legal developments in the PRC.

The PRC's economy differs from the economies of most developed countries in many respects, including the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC's economy has been transitioning from a planned economy to a more market-oriented economy since the late 1970s, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over the PRC's economic growth through allocating resources, controlling the incurrence and payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Changes in any of these policies, laws and regulations could adversely affect the economy in the PRC and could have a material adverse effect on our business.

The PRC government has implemented various measures to encourage foreign investment and sustainable economic growth and to guide the allocation of financial and other resources. However, we cannot assure you that the PRC government will not repeal or alter these measures or introduce new measures that will have a negative effect on us. PRC's social and political conditions may change and become unstable. Any sudden changes to PRC's political system or the occurrence of widespread social unrest could have a material adverse effect on our business and results of operations.

Uncertainties with respect to the PRC legal system could adversely affect us.

The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws and regulations governing economic matters generally. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investments in the PRC. However, the PRC has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in the PRC. In particular, the interpretation and enforcement of these laws and regulations involve uncertainties. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory provisions and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, these regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us.

Furthermore, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. In addition, any administrative and court proceedings in the PRC may be protracted, resulting in substantial costs and diversion of resources and management attention.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in the PRC against us or our management named in the report based on foreign laws.

We conduct substantially all of our operations in the PRC, and substantially all of our assets are located in the PRC. In addition, all of our officers and directors are PRC nationals and reside within PRC. As a result, it may be difficult for our shareholders to effect service of process upon us or our directors and officers inside the PRC. In addition, the PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts with the Cayman Islands and many other countries and regions. Therefore, recognition and enforcement in the PRC of judgments of a court in any of these non-PRC jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or impossible.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We rely principally on dividends and other distributions on equity from our PRC subsidiaries for our cash requirements, including for services of any debt we may incur.

Our PRC subsidiaries' ability to distribute dividends is based upon their distributable earnings. Current PRC regulations permit our PRC subsidiaries to pay dividends to their respective shareholders only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries, as a Foreign Invested Enterprise, or FIE, are required to draw 10% of its after-tax profits each year, if any, to fund a common reserve, which may stop drawing its after-tax profits if the aggregate balance of the common reserve has already accounted for over 50 percent of its registered capital. These reserves are not distributable as cash dividends. If our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us. Any limitation on the ability of our PRC subsidiaries to distribute dividends or other payments to their respective shareholders could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends or otherwise fund and conduct our business.

In addition, the Enterprise Income Tax Law and its implementation rules provide that a withholding tax rate of up to 10% will be applicable to dividends payable by Chinese companies to non-PRC-resident enterprises unless otherwise exempted or reduced according to treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC resident enterprises are incorporated.

PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay us from using the proceeds of future securities offerings to make loans or additional capital contributions to our PRC subsidiaries, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

Any funds we transfer to our PRC subsidiaries, either as a shareholder loan or as an increase in registered capital, are subject to approval by or registration with relevant governmental authorities in the PRC. According to the relevant PRC regulations on foreign-invested enterprises, or FIEs, in the PRC, capital contributions to our PRC subsidiaries are subject to the approval of or filing with the Ministry of Commerce, or MOFCOM or its local branches and registration with a local bank authorized by the State Administration of Foreign Exchange, or SAFE. In addition, (i) a foreign loan of less one year duration procured by our PRC subsidiaries is required to be registered with SAFE or its local branches and (ii) a foreign loan of one year duration or more procured by our PRC subsidiaries is required to be applied to the NDRC in advance for undergoing recordation registration formalities. Any medium or long-term loan to be provided by us to our PRC operating subsidiaries, must be registered with the NDRC and the SAFE or its local branches. We may not be able to complete such registrations on a timely basis, with respect to future capital contributions or foreign loans by us to our PRC subsidiaries. If we fail to complete such registrations, our ability to use the proceeds of any future securities offerings and to capitalize our PRC operations may be negatively affected, which could adversely affect our liquidity and our ability to fund and expand our business.

On March 30, 2015, the SAFE promulgated the Circular on Reforming the Management Approach Regarding the Foreign Exchange Capital Settlement of Foreign-Invested Enterprises, or SAFE Circular 19, which took effect as of June 1, 2015. SAFE Circular 19 launched a nationwide reform of the administration of the settlement of the foreign exchange capitals of FIEs and allows FIEs to settle their foreign exchange capital at their discretion, but continues to prohibit FIEs from using the Renminbi fund converted from their foreign exchange capital for expenditure beyond their business scopes, providing entrusted loans or repaying loans between nonfinancial enterprises. The SAFE issued the Circular on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts, or SAFE Circular 16, effective in June 2016. Pursuant to SAFE Circular 16, enterprises registered in China may also convert their foreign debts from foreign currency to Renminbi on a self-discretionary basis. SAFE Circular 16 provides an integrated standard for conversion of foreign exchange under capital account items (including but not limited to foreign currency capital and foreign debts) on a self-discretionary basis which applies to all enterprises registered in China. SAFE Circular 16 reiterates the principle that Renminbi converted from foreign currency-denominated capital of a company may not be directly or indirectly used for purposes beyond its business scope or prohibited by PRC laws or regulations, while such converted Renminbi shall not be provided as loans to its non-affiliated entities. On October 23, 2019, the SAFE issued the Notice of the State Administration of Foreign Exchange on Further Facilitating Cross-border Trade and Investment, or the SAFE Circular 28, which, among other things, expanded the use of foreign exchange capital to domestic equity investment area. The foreign-invested enterprises, whose business scope do not include equity investment, are allowed to lawfully make domestic equity investments by using their capital on the premise without violation to prevailing special administrative measures for access of foreign investments (negative list) and the authenticity and compliance with the regulations of domestic investment projects. As this circular is relatively new, there remains uncertainty as to its interpretation and application and any other future foreign exchange related rules. Violations of these Circulars could result in severe monetary or other penalties. SAFE Circular 19, SAFE Circular 16 and SAFE Circular 28 may significantly limit our ability to use Renminbi converted from the net proceeds of future securities offerings to fund our PRC subsidiaries, to invest in or acquire any other PRC companies through our PRC subsidiaries, which may adversely affect our business, financial condition and results of operations.

Although the audit report included in this report was issued by U.S. auditors who are currently inspected by the PCAOB, if it is later determined that the PCAOB is unable to inspect or investigate our auditor completely, investors would be deprived of the benefits of such inspection and our Ordinary Shares may be delisted or prohibited from trading.

The audit report included in this report for our 2022 and 2021 fiscal year was issued by Kreit & Chiu CPA LLP ("KC"), a U.S.-based accounting firm that is registered with the PCAOB and can be inspected by the PCAOB. The audit report included in this report for our 2020 fiscal year was issued by Briggs & Veselka Co. ("B&V"), which was also a U.S.-based accounting firm that was registered with the PCAOB and can be inspected by the PCAOB. We have no intention of engaging any auditor not based in the U.S. and not subject to regular inspection by the PCAOB. As an auditor of companies that are registered with the SEC and publicly traded in the United States and a firm registered with the PCAOB, KC is required under the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. If we were to engage a different auditor at any time in the future, we would engage an auditor that is U.S.-based and subject to full PCAOB inspection with all materials related to the audit of our financial statements accessible to the PCAOB. There is no guarantee, however, that any future auditor engaged by the Company would remain subject to full PCAOB inspection during the entire term of our engagement. In such case, we will engage a new qualified and fully inspected auditor, which may result in us delaying or restating our financial statements.

The PCAOB was unable to conduct inspections in the PRC without the approval of Chinese government authorities. If it is later determined that the PCAOB is unable to inspect or investigate our auditor completely, investors may be deprived of the benefits of such inspection. Any audit reports not issued by auditors that are completely inspected by the PCAOB, or a lack of PCAOB inspections of audit work undertaken in the PRC that prevents the PCAOB from regularly evaluating our auditors' audits and their quality control procedures, could result in a lack of assurance that our financial statements and disclosures are adequate and accurate.

As part of a continued regulatory focus in the U. S. on access to audit and other information currently protected by national law, in particular PRC's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress which, if passed, would require the SEC to maintain a list of issuers for which PCAOB was not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges ("EQUITABLE") Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges such as the Nasdaq of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted. Furthermore, there have been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On May 20, 2020, the U.S. Senate passed the Holding Foreign Companies Accountable Act (the "HFCAA"), which includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction. The U.S. House of Representatives passed the HFCAA on December 2, 2020, and the HFCAA was signed into law on December 18, 2020. Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and department with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. In response, on November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks. On December 2, 2021, the SEC adopted final rules relating to the implementation of certain disclosure and documentation requirements of the HFCAA. We will be required to comply with these rules if the SEC identifies us as having a "non-inspection" year (as defined in the interim final rules) under a process to be subsequently established by the SEC. The SEC is assessing how to implement other requirements of the HFCAA, including the listing and trading prohibition requirements described above. Under the HFCAA, our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not able to be inspected by the PCAOB for three consecutive years, and this ultimately could result in our Ordinary Shares being delisted. Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act ("AHFCAA"), which, if enacted, would amend the HFCAA and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not able to be inspected by the PCAOB for two consecutive years instead of three. On September 22, 2021, the PCAOB adopted a final rule implementing the HFCAA, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCAA, whether PCAOB is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction. On December 16, 2021, the PCAOB issued a Determination Report which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in: (1) mainland China of the People's Republic of China, because of a position taken by one or more authorities in mainland China; and (2) Hong Kong, a Special Administrative Region and dependency of the PRC, because of a position taken by one or more authorities in Hong Kong. On December 23, 2022, the AHFCAA was enacted, which amended the HFCAA by requiring the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three, thus reducing the time period for triggering the prohibition on trading. On August 26, 2022, the China Securities Regulatory Commission (the "CSRC"), the Ministry of Finance of the PRC (the "MOF"), and the PCAOB signed a Statement of Protocol (the "Protocol"), governing inspections and investigations of audit firms based in mainland China and Hong Kong, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. Pursuant to the fact sheet with respect to the Protocol disclosed by the SEC, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation and has the unfettered ability to transfer information to the SEC. On December 15, 2022, the PCAOB determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and voted to vacate its previous determinations to the contrary. However, should PRC authorities obstruct or otherwise fail to facilitate the PCAOB's access in the future, the PCAOB will consider the need to issue a new determination.

Our securities may be delisted under the HFCAA if the PCAOB is unable to inspect auditors with presence in China for three consecutive years. The delisting of our securities, or the threat of their being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives our investors of the benefits of such inspections.

The above recent developments may have added uncertainties to our ability to continue to list on Nasdaq or to offer our securities and we cannot assure you whether Nasdaq or other regulatory authorities would apply additional and more stringent criteria to us since we are an emerging growth company and substantially all of our operations are conducted in China. The SEC may propose additional rules or guidance that could impact us if our auditor is not subject to PCAOB inspection.

Moreover, on December 29, 2022, legislation entitled "Consolidated Appropriations Act, 2023" (the "Consolidated Appropriations Act") was signed into law by President Biden. The Consolidated Appropriations Act contained, among other things, an identical provision to the HFCAA, which reduces the number of consecutive non-inspection years required for triggering the prohibitions under the HFCAA from three years to two.

If our Ordinary Shares are unable to be listed on another securities exchange by then, such a delisting would substantially impair your ability to sell or purchase our Ordinary Shares when you wish to do so, and the risk and uncertainty associated with a potential delisting would have a negative impact on the price of our Ordinary Shares.

We are a "controlled company" within the meaning of the Nasdaq listing rules, and may follow certain exemptions from certain corporate governance requirements that could adversely affect our public shareholders.

Our largest shareholder, Mr. Yongjun Liu, owns more than a majority of the voting power of our outstanding Ordinary Shares. Under the Nasdaq listing rules, a company of which more than 50% of the voting power is held by an individual, group, or another company is a "controlled company" and is permitted to phase in its compliance with the independent committee requirements. Although we do not intend to rely on the "controlled company" exemptions under the Nasdaq listing rules even if we are deemed a "controlled company," we could elect to rely on these exemptions in the future. If we were to elect to rely on the "controlled company" exemptions, a majority of the members of our board of directors might not be independent directors and our nominating and corporate governance and compensation committees might not consist entirely of independent directors. Accordingly, if we rely on the exemptions, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, you would not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

Fluctuations in exchange rates could have a material and adverse effect on our results of operations and the value of your investment.

The value of the Renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy adopted by the PRC government. It is difficult to predict how long such appreciation of RMB against the U.S. dollar may last and when and how the relationship between the RMB and the U.S. dollar may change again. All of our revenues and substantially all of our costs are denominated in Renminbi. We rely on dividends paid by our operating subsidiaries in China for our cash needs. Any significant revaluation of Renminbi may materially and adversely affect our results of operations and financial position reported in Renminbi when translated into U.S. dollars, and the value of, and any dividends payable on, the Ordinary Shares in U.S. dollars. To the extent that we need to convert U.S. dollars into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we would receive. Conversely, if we decide to convert our Renminbi into U.S. dollars for the purpose of making payments for dividends on our Ordinary Shares or for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amount.

Governmental control of currency conversion may limit our ability to utilize our revenues effectively and affect the value of your investment.

The PRC government imposes controls on the convertibility of the Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. We receive substantially all of our revenues in Renminbi. Under our current corporate structure, we primarily rely on dividend payments from our PRC subsidiaries to fund any cash and financing requirements we may have. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval of SAFE by complying with certain procedural requirements. Specifically, under the existing exchange restrictions, without prior approval of SAFE, cash generated from the operations of our PRC subsidiaries in China may be used to pay dividends to our company. However, approval from or registration with appropriate government authorities is required, in principle, where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. As a result, we need to obtain SAFE approval to use cash generated from the operations of our PRC subsidiaries to pay off their respective debt in a currency other than Renminbi owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than Renminbi. The PRC government may at its discretion restrict access to foreign currencies for current account transactions in the future. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the Ordinary Shares.

Any failure to comply with PRC regulations regarding cybersecurity and data protection may subject us to fines and other legal or administrative sanctions, claims or legal proceedings.

The PRC Criminal Law, as amended by its Amendment 7 (effective on February 28, 2009) and Amendment 9 (effective on November 1, 2015), prohibits institutions, companies and their employees from selling or otherwise illegally disclosing a citizen's personal information obtained during the course of performing duties or providing services, or obtaining such information through theft or other illegal means. On November 7, 2016, the Standing Committee of the National People's Congress of the PRC issued the Cyber Security Law of the PRC, or Cyber Security Law, which became effective on June 1, 2017. Pursuant to the Cyber Security Law, network operators must not collect users' personal information without their consent and may only collect users' personal information necessary to the provision of services. Providers are also obliged to provide security maintenance for their products and services and shall comply with provisions regarding the protection of personal information as stipulated under the relevant laws and regulations. The Civil Code of the PRC (issued by the National People's Congress of the PRC on May 28, 2020 and effective from January 1, 2021) provides the main legal basis for privacy and personal information infringement claims under PRC civil law.

PRC regulators, including the Cyberspace Administration of China (the "CAC"), the Ministry of Industry and Information Technology and the Ministry of Public Security, have been increasingly focused on regulation in areas of data security and data protection. The PRC regulatory requirements regarding cybersecurity are constantly evolving. For example, various PRC regulatory bodies, including the CAC, the Ministry of Public Security and the State Administration for Market Regulation ("SAMR"), have enforced data privacy and protection laws and regulations with varying and evolving standards and interpretations.

In April 2020, the PRC government promulgated the 2020 Cybersecurity Review Measures, which came into effect on June 1, 2020. In July 2021, the CAC and other related authorities released a draft amendment to the 2020 Cybersecurity Review Measures for public comments. On December 28, 2021, the PRC government promulgated the 2022 Cybersecurity Review Measures, which came into effect and replaced the 2020 Cybersecurity Review Measures on February 15, 2022. According to the 2022 Cybersecurity Review Measures, (i) critical information infrastructure operators that purchase network products and services and internet platform operators that conduct data processing activities shall be subject to cybersecurity review in accordance with the 2022 Cybersecurity Review Measures if such activities affect or may affect national security; and (ii) internet platform operators holding personal information of more than one million users and seeking to have their securities list on a stock exchange in a foreign country shall file for cybersecurity review with the Cybersecurity Review Office. Under the Regulation on Protecting the Security of Critical Information Infrastructure promulgated by the State Council on July 30, 2021, effective September 1, 2021, "critical information infrastructure" is defined as important network facilities and information systems in important industries and fields, such as public telecommunication and information services, energy, transportation, water conservancy, finance, public services, e-government and national defense, science, technology and industry, as well as other important network facilities and information systems that, in case of destruction, loss of function or leak of data, may severely damage national security, the national economy and the people's livelihood and public interests. As of the date of this Annual Report, neither we nor any of our PRC Subsidiaries has been informed by any PRC governmental authority that we or any of our PRC Subsidiaries is a "critical information infrastructure operator."

On November 14, 2021, the CAC released the Administrative Regulations on the Management of Network Data Security (Draft for comments) or the Draft Administrative Regulation. Under the Draft Administrative Regulation, (i) data processors, i.e., individuals and organizations who can decide on the purpose and method of their data processing activities at their own discretion, that process personal information of more than one million individuals shall apply for cybersecurity review before listing in a foreign country; (ii) foreign- listed data processors shall carry out annual data security evaluation and submit the evaluation report to the municipal cyberspace administration authority; and (iii) where the data processor undergoes merger, reorganization and subdivision that involves important data and personal information of more than one million individuals, the recipient of the data shall report the transaction to the in-charge authority at the municipal level.

According to the currently in-effect PRC laws and regulations, we believe that neither we nor any of our PRC Subsidiaries is subject to the cybersecurity review, reporting or other permission requirements by the CAC under the applicable PRC cybersecurity laws and regulations with respect to the offering of our securities or the business operations of our PRC Subsidiaries, because neither we nor any of our PRC Subsidiaries qualifies as a critical information infrastructure operator or has conducted any data processing activities that affect or may affect national security or holds personal information of more than one million users. Additionally, as of the date of this Annual Report, neither we nor any of our PRC Subsidiaries has been required by any PRC governmental authority to apply for cybersecurity review, nor have we or any of our PRC Subsidiaries received any inquiry, notice, warning, sanction in such respect or been denied permission from any PRC regulatory authority to list on U.S. exchanges. However, as PRC governmental authorities have significant discretion in interpreting and implementing statutory provisions and there remains significant uncertainty in the interpretation and enforcement of relevant PRC cybersecurity laws and regulations if the PRC regulatory authorities take a position contrary to ours, we cannot assure you that we or any of our PRC Subsidiaries will not be deemed to be subject to PRC cybersecurity review requirements under the 2022 Cybersecurity Review Measures or the Draft Administrative Regulations (if enacted), nor can we assure you that we or our PRC Subsidiaries would be able to pass such review. If we or any of our PRC Subsidiaries fails to receive any requisite permission or approval from the CAC for future offerings or the business operations of our PRC Subsidiaries, or the waiver for such permission or approval, in a timely manner, or at all, or inadvertently concludes that such permission or approval is not required, or if applicable laws, regulations or interpretations change and obligate us to obtain such permission or approvals in the future, we or our PRC Subsidiaries may be subject to fines, suspension of business, website closure, revocation of business licenses or other penalties, as well as reputational damage or legal proceedings or actions against us, which may have a material adverse effect on our business, financial condition or results of operations. In addition, we could become subject to enhanced cybersecurity review or investigations launched by PRC regulators in the future pursuant to new laws, regulations or policies.

As of the date of this Annual Report, we have not been involved in any investigations or become subject to a cybersecurity review initiated by the CAC, and we have not received any inquiry, notice, warning, sanctions in such respect or any regulatory objections with respect to our business operations or in connection with future offerings from the CAC. However, as the Cybersecurity Review Measures and the Draft Administrative Regulation were newly issued, there remain uncertainties as to how it would be interpreted and enforced, and to what extent it may affect us.

Certain PRC regulations may make it more difficult for us to pursue growth through acquisitions.

Among other things, the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors ("M&A Rules") and Anti-Monopoly Law of the People's Republic of China promulgated by the Standing Committee of the NPC which became effective in 2008 and amended in 2022 ("Anti-Monopoly Law"), established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. Such regulation requires, among other things, that State Administration for Market Regulation ("SAMR") be notified in advance of any change-of-control transaction in which a foreign investor acquires control of a PRC domestic enterprise or a foreign company with substantial PRC operations, if certain thresholds under the Provisions of the State Council on the Standard for Declaration of Concentration of Business Operators, issued by the State Council in 2008 and amended in 2018, are triggered. Moreover, the Anti-Monopoly Law requires that transactions which involve the national security, the examination on the national security shall also be conducted according to the relevant provisions of the State. In addition, PRC Measures for the Security Review of Foreign Investment which became effective in January 2021 require acquisitions by foreign investors of PRC companies engaged in military-related or certain other industries that are crucial to national security be subject to security review before consummation of any such acquisition. We may pursue potential strategic acquisitions that are complementary to our business and operations.

Complying with the requirements of these regulations to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval or clearance from the MOFCOM, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

PRC regulations relating to the establishment of offshore special purpose companies by PRC residents may subject our PRC resident beneficial owners or our PRC subsidiaries to liability or penalties, limit our ability to inject capital into our PRC subsidiaries, limit our PRC subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.

In July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles, or SAFE Circular 37, to replace the Notice on Relevant Issues Concerning Foreign Exchange Administration for Domestic Residents' Financing and Roundtrip Investment Through Offshore Special Purpose Vehicles, or SAFE Circular 75, which ceased to be effective upon the promulgation of SAFE Circular 37. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities) to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles, or SPVs, will be required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV is required to update its filed registration with the local branch of SAFE with respect to that SPV, to reflect any material change. Moreover, any subsidiary of such SPV in China is required to urge the PRC resident shareholders to update their registration with the local branch of SAFE. If any PRC shareholder of such SPV fails to make the required registration or to update the previously filed registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiary in China. On February 13, 2015, the SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, or SAFE Notice 13, which became effective on June 1, 2015. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under SAFE Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE.

Certain of our shareholders that we are aware of are subject to SAFE regulations, and we expect all of these shareholders will have completed all necessary registrations with the local SAFE branch or qualified banks as required by SAFE Circular 37. We cannot assure you, however, that all of these shareholders will continue to make required filings or updates in a timely manner, or at all. We can provide no assurance that we are or will in the future continue to be informed of identities of all PRC residents holding direct or indirect interest in our company. Any failure or inability by such shareholders to comply with SAFE regulations may subject us to fines or legal sanctions, such as restrictions on our cross-border investment activities or our PRC subsidiaries' ability to distribute dividends to, or obtain foreign exchange-denominated loans from, our company or prevent us from making distributions or paying dividends. As a result, our business operations and our ability to make distributions to you could be materially and adversely affected.

Furthermore, as these foreign exchange regulations are still relatively new and their interpretation and implementation have been constantly evolving, it is unclear how these regulations, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant government authorities. For example, we may be subject to a more stringent review and approval process with respect to our foreign exchange activities, such as remittance of dividends and foreign-currency-denominated borrowings, which may adversely affect our financial condition and results of operations. In addition, if we decide to acquire a PRC domestic company, we cannot assure you that we or the owners of such company, as the case may be, will be able to obtain the necessary approvals or complete the necessary filings and registrations required by the foreign exchange regulations. This may restrict our ability to implement our acquisition strategy and could adversely affect our business and prospects.

As of the date of this disclosure, to our knowledge these PRC resident shareholders have applied for foreign exchange registration under the SAFE Circular 37 and other related rules. Although they are in the process of making foreign exchange registration, they may still face the above said possible fines in accordance with the PRC Laws.

Failure to make adequate contributions to various employee benefit plans and withhold individual income tax on employees' salaries as required by PRC regulations may subject us to penalties.

Companies operating in the PRC are required to participate in various government-mandated employee benefit contribution plans, including certain social insurance, housing funds and other welfare-oriented payment obligations, and contribute to the plans in amounts equal to certain percentages of salaries, including bonuses and allowances, of our employees up to a maximum amount specified by the local government from time to time at locations where we operate our businesses. The requirement of employee benefit contribution plans has not been implemented consistently by the local governments in the PRC given the different levels of economic development in different locations. Companies operating in the PRC are also required to withhold individual income tax on employees' salaries based on the actual salary of each employee upon payment. We may be subject to late fees and fines in relation to the underpaid employee benefits and under-withheld individual income tax, our financial condition and results of operations may be adversely affected.

Any failure to comply with PRC regulations regarding the registration requirements for employee stock incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

Pursuant to the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly-Listed Company, promulgated by SAFE in 2012, or SAFE Notices No. 7, PRC citizens and non-PRC citizens who reside in China for a continuous period of no less than one year who participate in any stock incentive plan of an overseas publicly listed company offered to the director, supervisor, senior management and other employees of, and any individual who has labor relationship with its domestic affiliated entities are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. In addition, an overseas entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. We and our directors, executive officers and other employees who are PRC citizens or who reside in the PRC for a continuous period of no less than one year and who have been granted stock options are subject to these regulations. Failure to complete the SAFE registrations for our employee incentive plans may subject them to fines and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries and limit our PRC subsidiaries' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees under PRC law.

In addition, the State Administration of Taxation, or SAT, has issued certain circulars concerning employee stock options and restricted shares. Under these circulars, our employees working in the PRC who exercise stock options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiaries have obligations to file documents related to employee stock options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees who exercise their share options or are granted with restricted shares. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC governmental authorities.

U.S. regulatory bodies may be limited in their ability to conduct investigations or inspections of our operations in the PRC.

Any disclosure of documents or information located in the PRC by foreign agencies may be subject to jurisdiction constraints and must comply with the PRC's state secrecy laws, which broadly define the scope of "state secrets" to include matters involving economic interests and technologies. There is no guarantee that requests from U.S. federal or state regulators or agencies to investigate or inspect our operations will be honored by us, by entities who provide services to us or with whom we associate, without violating PRC legal requirements, especially as those entities are located in the PRC. Furthermore, under the current PRC laws, an on-site inspection of our facilities by any of these regulators may be limited or prohibited.

If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with its "*de facto* management body" within the PRC is considered a "resident enterprise" and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term "*de facto* management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State Administration of Taxation, or SAT, issued a circular, known as SAT Circular 82, which provides certain specific criteria for determining whether the "*de facto* management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular applies only to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "*de facto* management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "*de facto* management body" in China, and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in the PRC; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise's primary assets, accounting books and records, company seals, and board of directors and shareholder resolutions are located or maintained in the PRC; and (iv) at least 50% of voting board members or senior executives habitually reside in the PRC.

We believe our company is not a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "*de facto* management body." If the PRC tax authorities determine that our company is a PRC resident enterprise for enterprise income tax purposes, we would be subject to PRC enterprise income on our worldwide income at the rate of 25%. Furthermore, we would be required to withhold a 10% tax from dividends we pay to our shareholders that are non-resident enterprises. In addition, non-resident enterprise shareholders may be subject to PRC tax on gains realized on the sale or other disposition of the Ordinary Shares, if such income is treated as sourced from within the PRC. Furthermore, if we are deemed a PRC resident enterprise, dividends paid to our non-PRC individual shareholders and any gain realized on the transfer of the Ordinary Shares by such shareholders may be subject to PRC tax at a rate of 20% (which, in the case of dividends, may be withheld at source by us). These rates may be reduced by an applicable tax treaty, but it is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. Any such tax may reduce the returns on your investment in our Ordinary Shares.

We face uncertainty with respect to indirect transfers of equity interests in PRC resident enterprises by their non-PRC holding companies.

On February 3, 2015, the SAT issued the Public Notice Regarding Certain Corporate Income Tax Matters on Indirect Transfer of Properties by Non-Tax Resident Enterprises, or SAT Bulletin 7. SAT Bulletin 7 extends its tax jurisdiction to transactions involving the transfer of taxable assets through offshore transfer of a foreign intermediate holding company. In addition, SAT Bulletin 7 has introduced safe harbors for internal group restructurings and the purchase and sale of equity through a public securities market. SAT Bulletin 7 also brings challenges to both foreign transferor and transferee (or other person who is obligated to pay for the transfer) of taxable assets, as such persons need to determine whether their transactions are subject to these rules and whether any withholding obligation applies.

On October 17, 2017, the SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or SAT Bulletin 37, which came into effect on December 1, 2017. The SAT Bulletin 37 further clarifies the practice and procedure of the withholding of non-resident enterprise income tax.

Where a non-resident enterprise transfers taxable assets indirectly by disposing of the equity interests of an overseas holding company, which is an "Indirect Transfer," the non-resident enterprise as either transferor or transferee, or the PRC entity that directly owns the taxable assets, may report such Indirect Transfer to the relevant tax authority. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such Indirect Transfer may be subject to PRC enterprise income tax, and the transferee or other person who pays for the transfer is obligated to withhold the applicable taxes currently at a rate of 10% for the transfer of equity interests in a PRC resident enterprise. Both the transferor and the transferee may be subject to penalties under PRC tax laws if the transferee fails to withhold the taxes and the transferor fails to pay the taxes.

We face uncertainties as to the reporting and other implications of certain past and future transactions where PRC taxable assets are involved, such as offshore restructuring, sale of the shares in our offshore subsidiaries and investments. Our company may be subject to filing obligations or taxed if our company is transferor in such transactions and may be subject to withholding obligations if our company is transferee in such transactions, under SAT Bulletin 7 and/or SAT Bulletin 37. For transfer of shares in our company by investors who are non-PRC resident enterprises, our PRC subsidiaries may be requested to assist in the filing under SAT Bulletin 7 and/or SAT Bulletin 37. As a result, we may be required to expend valuable resources to comply with SAT Bulletin 7 and/or SAT Bulletin 37 or to request the relevant transferors from whom we purchase taxable assets to comply with these circulars, or to establish that our company should not be taxed under these circulars, which may have a material adverse effect on our financial condition and results of operations.

Risks Related to Our Ordinary Shares

The market price for our Ordinary Shares may be volatile.

The trading prices of our Ordinary Shares are likely to be volatile and could fluctuate widely due to factors beyond our control. This may happen because of broad market and industry factors, like the performance and fluctuation in the market prices or the underperformance or deteriorating financial results of internet or other companies based in China that have listed their securities in the United States in recent years. The securities of some of these companies have experienced significant volatility since their initial public offerings, including, in some cases, substantial price declines in their trading prices. The trading performances of other Chinese companies' securities after their offerings, including internet and e-commerce companies, may affect the attitudes of investors toward Chinese companies listed in the United States, which consequently may impact the trading performance of our Ordinary Shares, regardless of our actual operating performance. In addition, any negative news or perceptions about inadequate corporate governance practices or fraudulent accounting, corporate structure or other matters of other Chinese companies may also negatively affect the attitudes of investors towards Chinese companies in general, including us, regardless of whether we have conducted any inappropriate activities. In addition, securities markets may from time to time experience significant price and volume fluctuations that are not related to our operating performance, such as the large decline in share prices in the United States, China and other jurisdictions in late 2008, early 2009 and the second half of 2011, which may have a material adverse effect on the market price of our Ordinary Shares.

In addition to the above factors, the price and trading volume of our Ordinary Shares may be highly volatile due to multiple factors, including the following:

- regulatory developments affecting us, our consumers, or our industry;
- conditions in the medical supplies business and the public perception of the legitimacy and ethics of certain business practices of our competitors or other market players within the industry;
- announcements of studies and reports relating to the quality of our product and service offerings or those of our competitors;
- changes in the economic performance or market valuations of other medical supplies businesses;
- actual or anticipated fluctuations in our quarterly results of operations and changes or revisions of our expected results;
- changes in financial estimates by securities research analysts;
- announcements by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- additions to or departures of our senior management;
- detrimental negative publicity about us, our management or our industry;
- fluctuations of exchange rates between the Renminbi and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding Ordinary Shares; and
- sales or perceived potential sales of additional Ordinary Shares.

The trading market for our Ordinary Shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who cover us downgrade shares or publish inaccurate or unfavorable research about our business, the market price for our Ordinary Shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our Ordinary Shares to decline.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our Ordinary Shares, the market price for our Ordinary Shares and trading volume could decline.

The trading market for our Ordinary Shares are influenced by research or reports that industry or securities analysts publish about our business. If industry or securities analysts decide to cover us and in the future downgrade our Ordinary Shares, the market price for our Ordinary Shares would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the market price or trading volume for our Ordinary Shares to decline.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our Ordinary Shares for return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Ordinary Shares as a source for any future dividend income.

Our board of directors has discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or share premium; provided that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in our Ordinary Shares will likely depend entirely upon any future price appreciation of our Ordinary Shares. There is no guarantee that our Ordinary Shares will appreciate in value or even maintain the price at which you purchased our Ordinary Shares. You may not realize a return on your investment in our Ordinary Shares and you may even lose your entire investment in our Ordinary Shares.

Substantial future sales or perceived potential sales of Ordinary Shares in the public market could cause the price of our Ordinary Shares to decline.

Sales of Ordinary Shares in the public market, or the perception that these sales could occur, could cause the market price of our Ordinary Shares to decline. As of the date of this report, we have 23,940,000 Ordinary Shares outstanding. All of the 3,940,000 Ordinary Shares sold in our recent initial public offering are freely transferable without restriction or additional registration under the Securities Act of 1933, as amended, or the Securities Act. All of our executive officers and directors and shareholders holding at least ten percent of our Ordinary Shares have agreed not to sell our Ordinary Shares for a period of 365 days following the effective date of our recent IPO, subject to extension under specified circumstances. Ordinary Shares subject to these lock-up agreements become eligible for sale in the public market upon expiration of these lock-up agreements, subject to volume and other restrictions as applicable under Rules 144 and 701 under the Securities Act. To the extent shares are released before the expiration of the lock-up period and sold into the market, the market price of our Ordinary Shares could decline. Moreover, the perceived risk of this potential dilution could cause shareholders to attempt to sell their shares and investors to short our Ordinary Shares. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

We may need additional capital and may sell additional Ordinary Shares or other equity securities or incur indebtedness, which could result in additional dilution to our shareholders or increase our debt service obligations.

We may require additional cash resources due to changed business conditions or other future developments, including any investments or acquisitions we may decide to pursue. If our cash resources are insufficient to satisfy our cash requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity securities or equity-linked debt securities could result in additional dilution to our shareholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot assure you that financing will be available in amounts or terms acceptable to us, if at all.

Certain existing shareholders have substantial influence over our company and their interests may not be aligned with the interests of our other shareholders.

Our directors and officers collectively own an aggregate of 66.56% of the total voting power of our outstanding Ordinary Shares. As a result, they have substantial influence over our business, including significant corporate actions such as mergers, consolidations, election of directors and other significant corporate actions.

They may take actions that are not in the best interest of us or our other shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our company, which could deprive our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and may reduce the price of our Ordinary Shares. These actions may be taken even if they are opposed by our other shareholders. In addition, the significant concentration of share ownership may adversely affect the trading price of our Ordinary Shares due to investors' perception that conflicts of interest may exist or arise.

We are an emerging growth company within the meaning of the Securities Act and may take advantage of certain reduced reporting requirements.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements applicable to other public companies that are not emerging growth companies including, most significantly, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 so long as we are an emerging growth company. As a result, if we elect not to comply with such auditor attestation requirements, our investors may not have access to certain information they may deem important.

In addition, under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of an exemption that allows us to delay adopting new or revised accounting standards until such time as those standards apply to private companies. As a result, we will not be subject to the same new or revised accounting standards as other public companies that comply with the public company effective dates. We have also elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result of these elections, the information that we provide to our stockholders may be different than you might receive from other public reporting companies.

We are a foreign private issuer within the meaning of the rules under the Exchange Act and, as such, we are exempt from certain provisions applicable to U.S. domestic public companies.

Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the securities rules and regulations in the United States that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD.

We are required to file an annual report on Form 20-F within four months of the end of each fiscal year. In addition, we intend to publish our financial results on a semi-annual basis in the form of press releases, distributed pursuant to the rules and regulations of the Nasdaq Global Market. Press releases relating to financial results and material events will also be furnished to the SEC on Form 6-K. However, the information we are required to file with or furnish to the SEC will be less extensive and less timely compared to that required to be filed with the SEC by U.S. domestic issuers. As a result, you may not be afforded the same protections or information that would be made available to you were you investing in a U.S. domestic issuer.

As a company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq Global Market corporate governance requirements; these practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq Global Market corporate governance requirements. However, presently, we do not have any immediate plans to rely on home country practice with respect to our corporate governance.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a foreign private issuer and, therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. We would lose our foreign private issuer status if, for example, more than 50% of our Ordinary Shares are directly or indirectly held by residents of the U.S. and we fail to meet additional requirements necessary to maintain our foreign private issuer status. In the future, if we lose our foreign private issuer status as of the last date of our second fiscal quarter, we would be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on the following January 1, which are more detailed and extensive than the forms available to us as a foreign private issuer. In such case, we would also have to comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders would become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq Global Market listing rules. As a U.S. listed public company that is not a foreign private issuer, we would incur significant additional legal, accounting and other expenses that we do not presently incur as a foreign private issuer listed on a U.S. securities exchange.

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

Prior to our initial public offering in February of 2022, we were a private company with limited accounting personnel and other resources with which to address our internal controls and procedures. Since then, we have been in a continuing process to develop, establish, and put in place a system to maintain internal controls and procedures that will allow our management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting if and when required to do so under Section 404 of the Sarbanes-Oxley Act of 2002. Although our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act until the date we are no longer an emerging growth company, our management will be required to report on our internal controls over financial reporting under Section 404.

As of December 31, 2022, our management assessed the effectiveness of our internal control over financial reporting. The material weaknesses relate to the fact that the Company does not have accounting personnel with sufficient knowledge of U.S. GAAP and SEC reporting procedures. Management concluded that as of December 31, 2022, our internal control over financial reporting were ineffective.

In order to address and resolve the foregoing material weakness, we have implemented measures designed to improve our internal control over financial reporting to remediate this material weakness, including hiring Shanghai Bluehill Advisory Co., Ltd. as our consultant and who has the requisite training and experience in the preparation of financial statements in compliance with applicable SEC requirements. With the assistance of our consultant, we are currently in compliance with U.S. GAAP and SEC reporting requirements. In addition to hiring an outside consultant, we also plan to take remedial measures including (i) hiring more qualified accounting personnel with relevant U.S. GAAP and SEC reporting experience and qualifications to strengthen the financial reporting function and to set up a financial and system control framework; (ii) implementing regular and continuous U.S. GAAP accounting and financial reporting training programs for our accounting and financial reporting personnel; and (iii) setting up an internal audit function as well as engaging an external consulting firm to assist us with assessment of Sarbanes-Oxley compliance requirements and improvement of overall internal control.

The implementation of these measures may not fully address the material weaknesses in our internal control over financial reporting, and we cannot conclude that they have been fully remedied. Our failure to correct theses material weaknesses or our failure to discover and address any other material weaknesses could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. As a result, our business, financial condition, results of operations and prospects, as well as the trading price of our Ordinary Shares, may be materially and adversely affected. Moreover, ineffective internal control over financial reporting significantly hinders our ability to prevent fraud. In addition, once we cease to be an "emerging growth company" as such term is defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, as a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Meihua is a holding company incorporated under the laws of the Cayman Islands on November 10, 2020 by our shareholder Yongjun Liu. Meihua's direct subsidiary is Kang Fu International Medical, a Hong Kong company. Kang Fu International Medical was incorporated on October 13, 2015 by four shareholders, Yongjun Liu, Yin Liu, Ace Capital Limited and King Tai International Holding Limited. On November 22, 2019, Yongjun Liu acquired 9,300,000 shares from Ace Capital Limited and 4,500,000 shares from King Tai International Holding Limited, respectively. Upon consummation of such share transfer, Yongjun Liu and Yin Liu constituted all of the shareholders of Kang Fu International Medical, holding 100% shares of Kang Fu International Medical. On December 21, 2020, Meihua in turn acquired 41,400,000 shares (or 69%) from Yongjun Liu and 18,600,000 shares (or 31%) from Yin Liu, respectively, resulting in Kang Fu International Medical becoming Meihua's wholly owned subsidiary. In exchange for the acquisition on Kang Fu, Meihua issued a total of 15,935,000 Ordinary Shares to Mr. and Mrs. Liu, who in turn transferred their shares to their wholly-owned holding company, Bright Accomplish Limited, on December 21, 2020. Bright Accomplish Limited is Meihua's controlling shareholder, holding approximately 66.56% of Meihua's Ordinary Shares as of the date of this report.

Meihua is not a Chinese operating company but a Cayman Islands holding company with operations conducted by its subsidiaries located in mainland China. Meihua operates its business through its indirect subsidiaries in China. Below is a list of Meihua's operating subsidiaries in China:

- Yangzhou Huada Medical Device Co., Ltd., or Yangzhou Huada: a subsidiary wholly owned by Kang Fu International Medical and established in Yangzhou, Jiangsu Province, PRC on December 24, 2001 with a registered capital of $602,400, which manufactures and sells Class I disposable medical devices under our own brands, and distributes Class I and Class II disposable medical devices sourced from other manufacturers, to our domestic customers. Specifically, Yangzhou Huada mainly focuses on the manufacturing, sales and distributions of non-bottled products, such as brushes, ID bracelets for domestic sales.

- Jiangsu Yada Technology Group Co., Ltd., or Jiangsu Yada: a subsidiary wholly owned by Yangzhou Huada and established in Yangzhou, Jiangsu Province, PRC on December 5, 1991 with a registered capital of RMB51,390,000, which manufactures and sells Class I and Class II disposable medical devices under our own brands, and distributes Class I and Class II disposable medical devices sourced from other manufacturers, to our domestic and overseas customers. Specifically, Jiangsu Yada mainly focuses on overseas sales.

- Jiangsu Huadong Medical Device Industrial Co., Ltd., or Jiangsu Huadong: a subsidiary wholly owned by Jiangsu Yada and established in Yangzhou, Jiangsu Province, PRC on November 18, 2000 with a registered capital of RMB50,000,000, which manufactures and sells Class I, II and III disposable medical devices under our own brands, and distributes Class I, II and III disposable medical devices sourced from other manufacturers, to our domestic and overseas customers. Specifically, Jiangsu Huadong mainly focuses on the manufacturing, sales and distributions of polyethylene bottled products, such as eye drop bottles and tablet bottles.

- Yangzhou Guanghui Medical Technology Co., Ltd., or Guanghui: a subsidiary wholly owned by Jiangsu Huadong was established in Yangzhou, China on December 22, 2020 with a registered capital of RMB1,000,000, to mainly manufactures and sells Class II disposable medical devices. Guanghui has not conduct real business.

- Hainan Guoxie Technology Group Co., Ltd., or Hainan Guoxie: a subsidiary of which 55% of registered capital (subscribed but unpaid registered capital) was acquired by Kang Fu International Medical from an individual Qin Wang with nil consideration on July 6, 2022, in order to conduct local business activities in Hainan. Hainan Guoxie was established in Qionghai, Hainan Province, China on October 7, 2021 with a registered capital of RMB100,000,000. Further disclosure will be made in 6-K regarding the new controlling subsidiary.

Meihua owns 100% of Kang Fu International Medical. Kang Fu International Medical owns 100% of Yangzhou Huada and 55% of Hainan Guoxie. Yangzhou Huada owns 100% of Jiangsu Yada. Jiangsu Yada, in turn, owns 100% of Jiangsu Huadong. Jiangsu Huadong, in turn, owns 100% of the equity interests of Guanghui. The following diagram illustrates our corporate structure as of the date of this report, including our principal subsidiary and their respective principal subsidiaries.

The structure of cash flows within our organization, and a summary of the applicable regulations, is as follows:

1. Our equity structure is a direct holding structure, pursuant to which the overseas entity listed in the U.S., Meihua International Medical Technologies Co., Ltd. ("Meihua International"), directly controls Yangzhou Huada Medical Device Co., Ltd ("Yangzhou Huada") (the "WFOE") and other domestic operating entities which are directly owned through the Hong Kong company, Kang Fu International Medical Co., Limited ("Kang Fu").

2. Within our direct holding structure, the cross-border transfer of funds within our corporate group is legal and compliant with the laws and`regulations of the PRC. After foreign investors' funds enter Meihua International at the close of securities offerings, the funds can be directly transferred to Kang Fu, and then transferred to subordinate operating entities through the WFOE.

If the Company intends to distribute dividends, the Company will transfer the dividends to Kang Fu in accordance with the laws and regulations of the PRC, and then Kang Fu will transfer the dividends to Meihua International, and the dividends will be distributed from Meihua International to all shareholders respectively in proportion to the shares they hold, regardless of whether the shareholders are U.S. investors or investors in other countries or regions.

3. In the reporting periods presented in this Annual Report, no cash and other asset transfers have occurred among the Company and its subsidiaries are as summarized as below:

	For the year ended December 31, 2022 (in US$)		
Inter-company cash transfers:	**Meihua (Cayman)**	**Kang Fu International Medical (HK)**	**PRC subsidiaries**
Cash transferred from Meihua to Kang Fu International Medical (1)	$ (26,010,150)	$ 26,010,150	-
Cash transferred from Kang Fu International Medical to Meihua (2)	$ 390	$ (390)	-
Cash transferred from Kang Fu International Medical to PRC subsidiaries (3)	-	$ (20,389,970)	$ 20,389,970
Cash transferred from PRC subsidiaries to Kang Fu International Medical (4)	-	$ 130,000	$ (130,000)

(1) Meihua transferred $26,010,150 to Kang Fu International Medical as a working capital loan.
(2) Kang Fu International Medical transferred $390 to Meihua for repayment of a working capital loan.
(3) Kang Fu International Medical contributed $20,389,970 to PRC subsidiaries as a capital contribution.*
(4) Yangzhou Huada, one of the PRC subsidiaries, transferred $130,000 to Kang Fu International Medical as a working capital loan.

* On February 18, 2022, the Company closed its initial public offering of Ordinary Shares and received approximately US$35 million. In March and April 2022, the Company transferred approximately US$26.0 million to Kang Fu International Medical for working capital purpose then Kang Fu International Medical made capital injection in aggregated of approximately US$20.4 million to PRC subsidiaries - Yangzhou Huada and Hainan Guoxie.

	For the year ended December 31, 2021 (in US$)		
Inter-company cash transfers:	**Meihua (Cayman)**	**Kang Fu International Medical (HK)**	**PRC subsidiaries**
Cash transferred from Kang Fu International Medical to PRC subsidiaries (5)	-	$ (46,297)	$ 46,297
Cash transferred from PRC subsidiaries to Kang Fu International Medical (6)	-	$ 768,042	$ (768,042)

(5) Kang Fu International Medical transferred $46,297 to PRC subsidiaries for repayment of a working capital loan.
(6) Yangzhou Huada, one of the PRC subsidiaries, transferred $768,042 to Kang Fu International Medical as a working capital loan.

	For the year ended December 31, 2020 (in US$)		
Inter-company cash transfers:	**Meihua (Cayman)**	**Kang Fu International Medical (HK)**	**PRC subsidiaries**
Cash transferred from PRC subsidiaries to Kang Fu International Medical (7)	-	$ 499,998	$ (499,998)

(7) Yangzhou Huada, one of the PRC subsidiaries, transferred $499,998 to Kang Fu International Medical as a working capital loan.

4. No dividends or distributions of a subsidiary have been made to the Company for the years ended December 31, 2020, 2021 and 2022. For the foreseeable future, the Company intends to use the earnings for research and development, to develop new products and to expand its production capacity. As a result, we do not expect to pay any cash dividends for the near term.

Our PRC subsidiaries' ability to distribute dividends is based upon their distributable earnings. Current PRC regulations permit our PRC subsidiaries to pay dividends to their respective shareholders only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries is required to set aside at least 10% of its after-tax profits each year, if any, to fund a statutory reserve until such reserve reaches 50% of each of their registered capitals. These reserves are not distributable as cash dividends. See "*Regulations Relating to Dividend Distributions*" for more information.

To address persistent capital outflows and the RMB's depreciation against the U.S. dollar in the fourth quarter of 2016, the People's Bank of China and the State Administration of Foreign Exchange, or SAFE, have implemented a series of capital control measures in the subsequent months, including stricter vetting procedures for China-based companies to remit foreign currency for overseas acquisitions, dividend payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls and our PRC subsidiaries' dividends and other distributions may be subject to tightened scrutiny in the future. The PRC government also imposes controls on the conversion of RMB into foreign currencies and the remittance of currencies out of the PRC. Therefore, we may experience difficulties in completing the administrative procedures necessary to obtain and remit foreign currency for the payment of dividends from our profits, if any. Furthermore, if our subsidiaries in the PRC incur debt on their own in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments.

In addition, the Enterprise Income Tax Law and its implementation rules provide that a withholding tax at a rate of 10% will be applicable to dividends payable by Chinese companies to non-PRC-resident enterprises unless reduced under treaties or arrangements between the PRC central government and the governments of other countries or regions where the non-PRC resident enterprises are tax resident. Pursuant to the tax agreement between Mainland China and the Hong Kong Special Administrative Region, the withholding tax rate in respect to the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10%. However, if the relevant tax authorities determine that our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable withholding tax in the future. Accordingly, there is no assurance that the reduced 5% withholding rate will apply to dividends received by our Hong Kong subsidiary from our PRC subsidiaries. This withholding tax will reduce the amount of dividends we may receive from our PRC subsidiaries.

Recent Developments

Completion of the Initial Public Offering ("IPO")

On February 18, 2022, we closed our initial public offering ("IPO") of 3,940,000 Ordinary Shares, par value US$0.0005 per share at a public offering price of $10.00 per share, and our Ordinary Shares started to trade on the Nasdaq Global Market under the ticker symbol "MHUA" on February 16, 2022. We sold 3,600,000 shares pursuant to our underwriters' firm commitment, together with an additional 340,000 shares sold pursuant to the underwriters' partial exercise of their over-allotment option.

The total net proceeds to the Company from the IPO, after deducting discounts, expense allowance, and expenses, were approximately $34,576,000. At the closing of the IPO, the Company deposited $500,000 from the gross proceeds from the IPO into an escrow account established by Wilmington Trust, National Association, as escrow agent, for purpose of covering potential legal actions against Prime Number Capital LLC, as a representative of the Underwriters, pursuant to an indemnification escrow agreement.

As a result of certain developments related to the IPO, the Company may face certain legal liabilities and exposure. Specifically, during the roadshow leading up to the IPO, a Hong Kong investment company named Tai He was referred to the Company by Shengang, the Company's co-underwriter based in the PRC. Tai He, through negotiations with Shengang, asserted that it would participate in the IPO as an investor. As a development stage PRC medical device company, the Company's management had no experience in the U.S. capital markets and relied on its investment bankers and underwriters in providing guidance and advice concerning its U.S. public offering. Accordingly, the Company was unaware of the actual motives of Tai He. Based on the Company's trust in Shengang and given the circumstances that the Company was unable to make further verification, the Company hastily entered into the Tai He Agreements.

Pursuant to the Tai He Agreements, Tai He agreed to invest a minimum of $35 million in the IPO subject to the Company making a $7.0 million refundable deposit and advancing a $3.0 million service fee for investor relations and other services (together, the "Services") payable to Tai He. The Company, its affiliates and individual shareholders paid the $7.0 million Refundable Deposit and $3.0 million service fee to Tai He in several installments from January 27, 2022 to March 11, 2022. After March 11, 2022, the Company has made no other payments to, nor had any direct interaction with, Tai He, and, in actuality, the Company never directly communicated with Tai He during the negotiations, only communicating about Tai He and the Tai He Agreements through Shengang.

After the IPO, through the Company's internal risk control process, the Company learned that Tai He does not appear to be an investor in the Company and, when the Company attempted to inquire about it, Tai He refused to speak with the Company. Based on the facts as investigated and understood by the Company, the Company believes that it was defrauded by Tai He and that Tai He never actually invested $35 million in the IPO. In fact, the Company learned that Tai He made no investments in the Company at all, and Tai He has no involvement in the Company's IPO matters. In addition, the Refundable Deposit has not been repaid to the Company and no Services have been provided to the Company by Tai He. As a result, the Company believes that the Tai He Agreements may be deemed a fraud perpetrated by Tai He and Shengang against the Company by Tai He taking advantage of asymmetric information, including the Company's lack of knowledge and understanding of the US markets, IPO rules and processes, and the trust of the Company.

After consultation with professionals, the Company is now aware that the Tai He Agreements were required to be disclosed to the public and the Company believes that the agreements themselves are fraudulent and non-enforceable, and therefore the Company is disclosing the Tai He Agreements to meet the compliance requirements of the SEC. Further, the Company acknowledges that it had improperly relied on the advice, direction and counsel of Shengang when entering into the Tai He Agreements. The Company is now proactively working to terminate the Tai He Agreements and recover the monies already paid to Tai He by the Company. Due to uncertainty of collection, the Company has written off approximately $4.8 million deposit and fully expensed $2.3 million service fee paid by the Company to Tai He in the year ended December 31, 2022. The Company and its executive management team intends to cooperate with the SEC, as well as any other relevant authorities, to ensure that its investors' interests are protected while such matters are resolved.

Corporate Information

Our principal executive offices are located at 88 Tongda Road, Touqiao Town, Guangling District, Yangzhou, PRC. Our telephone number at this address is +86-0514-89800199. Our registered office in the Cayman Islands is currently located at the office of Sertus Incorporations (Cayman) Limited, Sertus Chambers, Governors Square, Suite #5-204, 23 Lime Tree Bay Avenue, P.O. Box 2547, Grand Cayman, KY1-1104, Cayman Islands, which may be changed from time to time at the discretion of directors. Our agent for service of process in the United States is The Crone Law Group P.C., 500 Fifth Ave, Suite 938, New York, NY 10110.

B. Business Overview

Overview

Meihua International is a Cayman Islands exempted company incorporated on November 10, 2020. Kang Fu International is our wholly owned subsidiary formed in Hong Kong on October 13, 2015. We operate our business through our operating subsidiaries in China, namely 1) Yangzhou Huada, a wholly foreign owned subsidiary of Kang Fu International Medical, formed on December 24, 2001, located in Yangzhou, Jiangsu Province, PRC; 2) Jiangsu Yada, a wholly owned subsidiary of Yangzhou Huada, formed on December 5, 1991, located in Yangzhou, Jiangsu Province, PRC; 3) Jiangsu Huadong, a wholly owned subsidiary of Jiangsu Yada, formed on November 18, 2000, located in Yangzhou, Jiangsu Province, PRC; and 4) Guanghui, a wholly owned subsidiary of Jiangsu Huadong, formed December 22, 2020.

Through our operating subsidiaries in the PRC, Yangzhou Huada, Jiangsu Yada and Jiangsu Huadong, we are mainly specialized in the research, development, manufacturing and sales of Class I, Class II and Class III disposable medical devices both domestically and internationally.

Pursuant to the Regulations on the Supervision and Administration of Medical Devices promulgated on January 4, 2000, which is effective on June 1, 2014 and amended by the State Council on May 4, 2017, medical devices are classified into the following three categories based on the degree of risk.

Class	Standard (per PRC National Medical Device Management regulations)
I	Class I medical devices shall refer to those devices with low level of risks and whose safety and effectiveness can be ensured through routine administration.
II	Class II medical devices shall refer to those devices with moderate risks that must be strictly controlled and regulated to ensure their safety and effectiveness.
III	Class III medical devices shall refer to those devices with relatively high risks that must be strictly controlled and regulated through special measures to ensure their safety and effectiveness.

We provide our customers with one-stop solution for a variety of safety and quality disposable medical devices. The safety and quality of disposable medical devices are always our core values. We attribute our success to our sustainable and organic growth driven by our capacity expansion based on market demand, our deep understanding of our target end markets and our sound relationships with our customers, distributors, independent sales agents, and suppliers.

Our Revenue Model

We generate revenues through 1) manufacturing and sales of Class I, II, III disposable medical devices under our own brands, 2) resales of Class I, II, III disposable medical devices sourced by us from other manufacturers. For the fiscal years ended December 31, 2022, 2021, and 2020, we recognized $103,346,341, $104,037,710, and $89,061,010, respectively, in revenues, of which our own brand sales accounted for 48.88%, 46.19%, and 49.94%, respectively, and the resales of sourced disposable medical devices from other manufactures accounted for 51.12%, 53.81%, and 50.06%, respectively.

Our disposable medical devices reach end users both domestically and internationally. For the fiscal years ended December 31, 2022, 2021, and 2020, our total sales to domestic direct end users customers and domestic distributor customers accounted for 99.52%, 85.78%, and 81.90% of our revenues, respectively. For the fiscal years ended December 31, 2022, 2021, and 2020, our sales to overseas distributing customers accounted for 0.48%, 14.22%, and 18.10%, respectively, of our revenues.

We sell disposable medical devices through our direct sales force and distributors. For the fiscal years ended December 31, 2022, 2021, and 2020, our sales through direct sale channels accounted for 9.16%, 9.13%, and10.59%, respectively, of our revenues, and our sales through distributors accounted for 90.84%, 90.87%, and 89.41%, respectively, of our revenues, of which domestic distributors accounted for 90.36%, 76.65%, and 71.31%, respectively, and exporting distributors accounted for 0.48%,14.22%, and 18.10%, respectively, of our revenues.

Our Products

Our products cover all regions of PRC. Internationally, our products are exported to more than 30 countries, including Europe, North America, South America, Asia, Africa, and Oceania.

Our current product portfolio (consisting of both self-manufactured and out-sourced products) includes: 1) Class I disposable medical devices, such as, disposable medical X-ray films, medical dry films, dry laser imagers, gauze bandages, examination gloves, pharmaceutical packaging materials and containers, low-density polyethylene (LDPE) bottles for eye drops, high-density polyethylene (HDPE) bottles for tablets, etc.; 2) Class II disposable medical devices, such as, disposable full anesthesia kits, medical brush, woman's examination kits, urethral catheterization kits, gynecological examination kits, endotracheal intubation, medical masks, anal bags, and suction connecting tube, etc.; and 3) Class III disposable medical devices, such as disposable infusion pumps, anesthesia puncture kits, electronic pumps, etc.

As of the date of this report, we have a total of 1,063 products in our product portfolio, including 937 products for domestic sales and 126 products for overseas sales.

Our top 20 products for the fiscal years ended December 31, 2022 and 2021 were as follows:

Class Category	Product Name	Image	Own brand / source from other	Use	% of Sales in 2022	% of Sales in 2021
Class II	Disposable ID bracelet		Own Brand	Identify patients	14.40%	13.07%
Class II	Disposable woman's examination kits		Own Brand	Gynecological examination	8.39%	5.55%
Class II	Disposable medical brush		Own Brand	Clean the test tube or plastic pipe	8.14%	7.16%
Class II	Medical kit		source from other	For operation	4.83%	3.86%
Class II	Medical sterile dressing surgical kits		Own brand	Use before operation	4.56%	3.81%

Class Category	Product Name	Image	Own brand / source from other	Use	% of Sales in 2021	% of Sales in 2020
Class II	Medical Brush		source from other	Hand wash before Operation	3.96%	4.10%
Class I	High-density polyethylene (HDPE) bottles for tablets		Own brand	Tablet bottles	3.13%	2.48%
Class II	Medical catheter		source from other	Use for catheterization	2.83%	3.46%
Class II	Uterine tissue suction tube		Own brand	Uterine tissue sampling	2.78%	3.44%
Other	Disposable plastic milk bottle		Own brand	Use for feeding	2.34%	1.49%

Class Category	Product Name	Image	Own brand / source from other	Use	% of Sales in 2021	% of Sales in 2020
Class I	Low-density polyethylene (LDPE) bottles for eye drops		Own brand	Eyedrop bottle	2.30%	2.78%
Class II	Disposable Gynecological sampler		Own brand	Getting samples during gynecological examination	1.92%	2.31%
Class II	Disposable medical brush (type B1)		Own brand	Hand wash before operation	1.48%	1.24%
Class II	Disposable anal bag		Own brand	For the rectal colon or ileum anal stoma postoperative patients and patients with urinary incontinence to collect feces and other feces care	1.44%	1.20%

Class Category	Product Name	Image	Own brand / source from other	Use	% of Sales in 2021	% of Sales in 2020
Class II	Disposable women's examination kits		source from other	Gynecological examination	1.25%	2.17%
Other	Nb / PSN rubber cover		Own brand	Use for capping	1.03%	1.04%
Class II	Disposable virus sampling tube		source from other	Used to hold test samples	0.74%	0.09%
Class II	Disposable humidified nasal oxygen tube		Own brand	Connect with oxygen supply device and used to moisten the patient and inject oxygen	0.58%	0.61%
Class II	Medical disposable protective clothing		source from other	protective suit	0.56%	0.06%
Class I	Throat strip		source from other	For throat surgery	0.54%	0.64%

As a medical device manufacturing and sales company, we are subject to extensive government regulation and supervision in the PRC. Pursuant to PRC laws, we must obtain production license for Class II and III disposable medical devices, operation license for Class III disposable medical devices, and filing or registration certificates for certain Class I, II or Class III disposable medical devices. As of the date of this report, we are current on all licenses and certificates and have obtained Class I, II and III disposable medical device qualifications in the PRC. Meanwhile, we have established a sound quality assurance system. We have received international "CE" certification and ISO 13485 system certification. We have also registered with the FDA (registration number: 3006554788) for over 20 products as of the date hereof, including but not limited to ID bracelets, surgical tapes, elastic and adhesive bandages, which are all FDA Class I products.

Our operating subsidiaries in the PRC focus on the manufacturing and sales of the disposable medical devices as follows:

Yangzhou Huada

Yangzhou Huada mainly manufactures and sells Class I disposable medical devices, such as disposable pharmaceutical packaging materials and containers using LDPE for eye drops and high-density polyethylene ("HDPE") bottles for tablets, as well as disposable plastic baby bottles, NB/PSN rubber covers and 8.2mL folded spoons for tools and containers, etc.

Additionally, Yangzhou Huada is also engaged in the resales of Class I and II disposable medical devices sourced from other manufacturers when we provide one-stop shopping experience to our customers.

As of the date of this report, Yangzhou Huada has no manufacturing activities for Class II and III disposable medical devices and its sales are limited to our domestic customers.

Jiangsu Yada

Jiangsu Yada mainly manufactures and sells both domestically and internationally 1) Class I disposable medical devices, such as medical dry imaging films; and 2) Class II disposable medical devices, such as disposable woman's examination kits, suction connecting tubes, and Class II 6866 medical polymer materials and products (including but not limited to transfusion equipment and pipelines, endotracheal intubation for respiratory anesthesia or ventilation), etc.

In addition to above, Jiangsu Yada is also engaged in the domestic and international resales of 1) Class I and Class II disposable medical devices sourced from other manufacturers when we provide one-stop shopping experience to our customers.

As of the date of this report, Jiangsu Yada has no manufacturing and sales activities for Class III disposable medical devices.

Jiangsu Huadong

Jiangsu Huadong mainly manufactures and sales both domestically and internationally 1) Class I medical devices, such as medical x-ray films, multi-functional self-extracting X-ray film machines, dry films for medical use, gauze bandages, examination gloves, etc.; 2) Class II medical devices, such as disposable full anesthesia kits, urethral catheterization kits, gynecological examination kits, endotracheal intubation, medical masks, and various tubes, etc.; and 3) Class III medical devices, such as disposable infusion pumps, anesthesia puncture kits, electronic pumps, etc.

In addition to above, Jiangsu Huadong is also engaged in the domestic and international resales of Class I, II and III medical devices sourced from other manufacturers when we provide one-stop shopping experience to our customers.

COVID-19 Pandemic Products

With the impact of the coronavirus disease 2019 (COVID-19) outbreak commencing in the first half of 2020, demand in products related to virus prevention and control surged worldwide. Although these products were not our mainstream products previously, we witnessed order surges and demand outstripped supply for several months starting in February 2020. For the fiscal year ended December 31, 2020, orders for masks and gloves were valued at $10.1 million and $2.4 million, respectively.

As of the date of this report, although the current market demand for certain virus prevention products is not as strong as that in 2020 in China due to the ongoing recovery from the COVID-19, awareness of protection against COVID-19 and other similarly situated droplet transmission diseases is to some extent rooted among people in China, resulting in continuing high demand among people for virus prevention and control products compared to previous years. Internationally, except for China, other countries are still in high demand of certain virus prevention products for the prevention and control of COVID-19. According to a COVID-19 vaccines update released by World Health Organization in December 2020, there are three COVID-19 vaccines for which certain national regulatory authorities have authorized the use. None have yet received WHO EUL/PQ authorization. The impact of COVID-19 vaccines on the pandemic will depend on several factors, such as the effectiveness of the vaccines; how quickly they are approved, manufactured, and delivered; and how many people get vaccinated. Most scientists anticipate that, like most other vaccines, COVID-19 vaccines will not be 100% effective. (Source: https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines?adgroupsurvey={adgroupsurvey}&gclid=CjwKCAiA_eb-BRB2EiwAGBnXXrbZVR1ojK9i13YVEq7Hg5YBAULf8ii7IRf8kxKBu3fQQVpzJ8iD9hoCtHUQAvD_BwE). As a result, we believe certain virus prevention products will still be in high demand due to the uncertainty surrounding the future severity of COVID-19 and the awareness of the general public towards the virus prevention. To anticipate and adapt to this new normal phase, the Company was building a 2,550 square meter of new factory for expanding the production scale of exporting products, located in Jiangsu Yada's factory plant. The Company received government approval on December 22, 2020 and has started construction. The Company has completed construction during the current year, with a total cost of approximately $1.2 million. The source of funds for the new factory comes mainly from bank loans. The Company has placed an order for 12 production lines, which will be installed in the new factory when construction is complete. The new production lines have an estimated cost of $3.71 million and will be used to produce medical and civil non-woven products for outbreak prevention, including masks, protective clothing and testing papers. The annual production capacity of the new production lines includes approximately 45 million masks, 2.7 million insulation suits, 1.5 million protection suits, 90 million testing papers, 0.6 million Minimally invasive high-value consumables. Starting from February 2020, we began to gradually add to the production line for masks and increase the production of masks. However, as the sales of masks is declining, our eight mask production lines have been shut down in the past year. Sales of masks for the year ended December 31, 2022, 2021, and 2020 were approximately $0.53 million, $1.02 million, and $10.1 million, respectively.

As the epidemic gradually flattens out, the needs for masks decreased. We have not generated material cost consumption on the production of masks and masks are not our main sales product. Accordingly, the decrease of demand for masks in 2022 and 2021 not have a material adverse effect on our revenue.

With additional capacity and a broad spectrum of product offerings, we are capable of providing tailored "one-stop" services to our customers, ranging from wound care, surgical auxiliary supplies to disease prevention.

Our One-stop Service

Our operating subsidiaries are located in Touqiao Town, Yangzhou City, Jiangsu Province, PRC ("Touqiao Town"), one of the four medical device centers in PRC. Touqiao Town is conferred on "Hometown of Medical Device & Consumables in China" by China Medical Device Industry Association and granted by the Jiangsu local government as one of the 25 nationally certified "Chinese Towns with Special Features" on medical devices. Hundreds of disposable medical device manufacturers have their facilities or offices in Touqiao Town and provide a variety of product offerings to more than 100 countries and areas, including United States, Europe, Africa, India, Brazil, etc. Lots of medical device professionals, including R&D and technology professionals and thousands of independent sales agents are also based in Touqiao Town, providing sufficient labor to local medical device companies.

Due to our unique geographical advantage, we are capable of providing one-stop service to our customers. By placing one single order with us, our customers will receive all products on their order even if there are more than 100 to 1000 different kinds of products on such order and some products are not in our product portfolio. Upon receipt of such orders, we are able to quickly fulfill the orders by including our own brand products in addition to qualified products sourced from other manufacturers in Touqiao Town.

Our one-stop service not only bring benefits and conveniences to our customers, but also reduces our procurement costs, such as transportation fee and travel fee, and mitigates the impact of raw material price fluctuations in the market, thus increasing our profit margins.

Our Customers

We have three types of customers, i) direct end user customers, which includes hospitals, pharmacies, and medical institutions, ii) domestic distributor customers, which distribute our products to end-user customers in China, and iii) export distributor customers, which distribute our products to end users customers in North America, Asia, South America, Africa and Oceania. As of December 31, 2022, the company had a total of 3,853 customers, of which 525 are direct end user customers, 3,004 are domestic distributors customers, and 324 are export distributors customers. Our direct end user customers, as well as substantially all of our domestic distributor customers and our export distributor customers, are based in China.

We do not have long-term written sales agreements with our customers. Each customer sale is typically governed by a brief purchase-order based sales agreement. The key terms of the sales agreements (including those agreements with our top customers) include:

- The product's name, type, quantity and price.
- Quality standard - medical device qualifications, including business license, medical device production and operation licenses, medical device registration certificates, inspection report, etc. Lack of one of the qualifications will result in termination of the agreements.
- Delivery method and payment terms. Payments are typically due within 90 days after delivery.
- Breach of contract terms, including refund and return of products. Purchasers are entitled to refunds and may return the product if the wrong product is delivered or the product does not meet agreed quality standards.
- Shipping costs are typically borne by the seller.
- Dispute solutions, including bringing a lawsuit at the local People's court if negotiations are unsuccessful.

For the fiscal years ended December 31, 2022, 2021, and 2020, the revenues generated from our direct end user customers and domestic distributor customers amounted to $102,845,751, $89,240,394, and $72,941,380, respectively, constituting approximately 99.52%, 85.78%, and 81.90%, respectively, of our total revenues, with export distributor customers accounting for $500,590, $14,797,316, and $16,119,630, respectively, constituting approximately 0.48%, 14.22%, and 18.10%, respectively, of our total revenues.

As we provide our products to export distributor customers based upon their regional coverage, we do not have country-specific information on end-users overseas. Substantially all end users who acquire our products through domestic distributors are based in China. End users who acquire our products through licensed export distributors have two types – foreign distributors from other countries and end users from other countries. For the fiscal year ended December 31, 2022, our total sales to the top two customers accounted for 27.63% and 10.97% of our revenues, respectively. The top two customers for the fiscal year ended December 31, 2022 were Customer A (a domestic distributor customer) and Customer C (a domestic distributor customer). Our top two customers for the years ended December 31, 2021 and 2020 were the same for both years. They were Customer A (a domestic distributor customer) and Customer B (an export distributor customer). For the year ended December 31, 2021, our total sales to the top two customers accounted for 21.91% and 11.26% of our revenues, respectively. For the year ended December 31, 2020, our total sales to the top two customers accounted for 17.68% and 12.71% of our revenues, respectively.

Our Suppliers

We source our suppliers through multiple channels: (i) through referrals from local medical device industry associations, (ii) through industry exhibitions/expos, (iii) through our distributors, and (iv) through open bids.

Our suppliers are divided into two categories: (1) those providing raw materials for the manufacturing of our products, and (2) those providing products for our resales.

Our raw and auxiliary materials include rubber, chemical polyethylene (PE), polyethylene, polypropylene, nylon and non-woven fabrics, all of which are purchased from certified and qualified suppliers in China. Our raw materials supply has been very stable for many years and are easily sourced due to our unique geographical location.

We distribute products sourced from certain suppliers when it comes to our one-stop service. We from time to time receive orders from our customers with a variety of products not in our product portfolio. Through our suppliers, we are capable of accommodating our customers' need and providing one-stop service to our customers.

We do not have long-term written purchase agreements with our suppliers. We do not consider any of our suppliers to be material to our business. As of the date of this report, we have a total number of 71 suppliers. We can utilize any supplier we determine at our sole discretion. Although we can utilize any supplier we determine, we believe that we established healthy and stable relationships with our significant suppliers through years of cooperation. These significant suppliers, in the aggregate, accounted for over 25% of our raw material purchases for the year ended December 31, 2022, 2021, and 2020. For the year ended December 31, 2022, our three significant suppliers are Yangzhou Tianyi Medical Instrument Co., Ltd., Yangzhou Xiaguang Medical Instrument Co., Ltd. and Yangzhou Jiangzhou Medical Instrument Co., Ltd. representing 11.93%, 7.58% and 7.01% of our total purchase respectively. For the year ended December 31, 2021, our three significant suppliers are Yangzhou Tianyi Medical Instrument Co., Ltd., Jiangsu Changfeng Medical Industry Co., Ltd. and Yangzhou Jiangzhou Medical Instrument Co., Ltd. representing 9.42%, 8.88% and 8.33% of our total purchase respectively. For the year ended December 31, 2020, our three significant suppliers are Yangzhou Xiaguang Medical Instrument Co., Ltd., Yangzhou Jiangzhou Medical Instrument Co., Ltd. Ltd. and Yangzhou Tianyi Medical Instrument Co., Ltd. representing 9.25%, 8.13% and 8.09% of our total purchase respectively. There are no minimum purchase requirements with any of our suppliers, including these significant ones. Each supplier order is typically governed by a brief purchase-order based purchase agreement. The key terms of the supplier purchase agreements (including those agreements with our significant suppliers) include:

- The product's name, type, quantity and price.
- The supply cooperation relationship of the parties. Some suppliers supply finished products for re-sale and others supply raw materials for manufacturing.
- Quality terms which are typically expressed with reference to national or industry standards.
- Delivery method and payment terms; typically, payment is due 90 days after delivery. Shipping costs are the responsibility of the supplier
- Breach of contract terms, including refund and return of products, compensatory damages. If the supplier cannot deliver the product within the time agreed, or if the products do not meet the stated quality standard, the supplier must compensate us for losses caused, including treble damages if the products are defective or counterfeit. In the event we cannot pay timely, liquidated damages are due to the supplier.
- For some significant supplier agreements, the breaching party is contractually required to pay 10% of the contract amount as liquidated damages if they unilaterally terminate the agreement. If the supplier fails to deliver the products within the time agreed, the supplier is contractually required to pay 5% of the contract amount on a daily basis for each and every date they delay delivery.

Marketing and Sales

We market and sell our products through multiple channels: (1) through direct sales force, including our own employees and independent sales agents, and (ii) through distribution network, including our domestic and exporting distributors.

Direct Sales Force

Our Sales Team

As of the date of this report, we have a direct sales team consisting of 81 employees. Our sales team provides us with direct access to our customers and is capable of addressing our customers' needs in a fast and efficient way. They also coordinate with our distributors and independent sales agents in marketing and sales of our products.

The compensation package for our sales team includes fixed base salaries and commissions of 0.5%-1.0% based on the revenues or collection they achieve. We provide our sales team with regular training and internally developed systems to assist them in quickly becoming proficient and productive sales personnel.

Independent Sales Agents

As of the date of this report, we have a large number of independent sales agents for the marketing and sales of our products in the Chinese market, covering all regions of the PRC. Our independent sale agents market and sell our products in the regions where they are located.

We have no written sale agent agreements with our independent sale agents and we are connected with them via oral agreements. Upon successful sales of our products to customers secured by them, they settle their commission with our customers. We do not provide any commission or make any payments to them.

Our direct sales force has secured a total of 525 domestic customers, including hospitals and medical institutions. We will continue to work with existing, and identify and secure new, independent sales agents, to expand our customer base and enhance our brand recognition across China.

Distribution Network

As of the date of this report, we have 3,004 domestic distributors and 324 exporting distributors. Distributors usually purchase products from us at a lower price and then resell our products to end customers both domestically and internationally at a comparatively higher price and earn the price difference.

Our domestic distributors cover 32 provincial-level administrative regions of PRC for the resales of our products in the Chinese market. They market and distribute our products in the regions where they locate and have secured approximately 5,884 domestic customers for us, including hospitals and medical institutions.

Our exporting distributors are limited to our overseas sales. Each of our exporting distributor usually sells medical devices to at least three overseas customers. We therefore estimate conservatively that the total number of established direct and indirect customer relationships established overseas through our exporting distributors in Europe, North America, South America, Asia, Africa, and Oceania to be about 915.

Distributors must have related qualifications in order to distribute our products. Upon our verification and approval by inspecting their qualification materials, such as business license, disposable medical device operation license, and medical device exporting license, etc., and verifying their sales channels, distribution capacity and business reputation, distributors are authorized to distribute our products to their domestic and overseas customers.

We do not have long-term written agreements with our distributors. Each distributor order is typically governed by a brief purchase-order based sales agreement. The key terms of the distributor purchase agreements include:

- The product's name, type, quantity and price.
- Quality standard - medical device qualifications, including business license, medical device production and operation licenses, medical device registration certificates, inspection report, etc. Lack of one of the qualifications will result in termination of the agreements.
- Delivery method and payment terms; payment is typically due within 90 days after delivery Shipping costs re typically borne by us.
- Breach of contract terms, including refund and return of products. Distributors are entitled to refunds and may return the product if the wrong product is delivered or the product does not meet agreed quality standards.
- Dispute solutions, including bringing a lawsuit at the local People's court.

Our distributors have secured a total of approximately 6,799 customers for us both domestically and internationally. We will continue to work with existing distributors, and identify and secure new distributors, to expand our customer base and enhance our brand recognition both in PRC and abroad.

Our Research and Development ("R&D")

We invest in R&D efforts that advance our technology with the goal to expand new products and improve upon our existing product offerings. Our R&D expenses totaled approximately $3.0 million, $2.7 million, and $2.5 million, for the years ended December 31, 2022, 2021, and 2020, respectively. R&D expenses mainly consist of applicable personnel, design, sample testing and materials expenses. As of the date of this report, we had a total of 30 employees in the R&D department. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products, enhance existing products and technologies and perform activities related to obtaining additional regulatory approval.

We adhere to a market-oriented R&D approach and actively cooperate with universities, hospitals, medical institutions, distributors and independent sales agents in sorting out our R&D orientation based on the real market demand. Our market-oriented R&D approach includes the following:

- *Hospitals to Factories*. There is usually a technology department or scientific research department in every hospital in China. Hospitals conduct R&D on innovative products due to their needs, but they normally have no manufacturing capabilities and qualifications. As a disposable medical device manufacturer, to serve our customers better, we from time to time communicate with hospital personnel and keep ourselves informed of their latest demands, including but not limited to acquiring the patents on their IP list required for the manufacturing of certain products, and research, develop and manufacture such products that tailored to their needs.
- *Universities to Factories.* A lot of universities and medical colleges have research centers, where they develop and patent certain R&D results. We from time to time communicate with their research personnel and keep ourselves informed of their latest R&D and patents, and if needed by our customers, purchase patents from them and research, develop and manufacture products with such patents.
- *Customers' Feedbacks from Distributors and Independent Sales Agents*. Distributors and independent sales agents from time to time receive feedbacks and proposals from end use customers and then pass on to us. Upon our internal evaluations on those feedbacks and proposals, we may either research, develop and improve our products accordingly, or entrust university or college research centers for R&D. Once we receive their R&D results, we may improve our products in accordance with their R&D results, including acquiring patents from those centers for manufacturing of our products.

By continuously upgrading and improving products and technologies that tailed to our customers' requirements, we have further strengthened our customer's loyalty.

As of the date of this report, we have 27 registered patents. Faced with the ever-changing market demands, we continue to abandon and phase out unsuitable patents and technologies, and simultaneously invest in acquiring new patents and technologies that tailored to our customer's fast changing requirements.

We believe our ability to rapidly develop innovative products is attributable to the dynamic product innovation process that we have implemented, the versatility and leveragability of our core technology and the management philosophy behind that process. We have recruited and retained professionals with significant experience in the development and improvement of medical devices. We have a pipeline of products in various stages of development that are expected to provide additional commercial opportunities. Our research and development efforts are based at our operating subsidiaries in PRC.

Competition

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete or plan to compete with manufacturers of disposable medical devices. Some of these competitors are large, well-capitalized companies with significantly greater market share and resources than we have. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. We also compete with smaller medical device companies that have single products or a limited range of products. Some of our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers and third-party payers;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent prosecution.

The Company believes that it competes favorably with respect to these factors, although there can be no assurance that the Company will be able to continue to compete successfully in the future.

We believe the following companies may be our competitors:

- Shandong Weigao Group Medical Polymer Co., Limited, is principally engaged in the research and development, production and sale of single-use medical devices. The Group has a wide range of products, which includes: i) consumables (infusion sets, syringes, medical needles, blood bags, pre-filled syringes, blood sampling products, and other consumables); ii) orthopedic materials and iii) blood purification consumables and equipment. Currently, its sales are mainly conducted in the PRC market, but it is actively exploring opportunities in international markets, with products having been exported to 30 countries and regions, including the United States, Germany, Romania, Australia and the United Kingdom. (Source: http://en.weigaogroup.com/gfccontentEn/Enterpr.aspx)
- Jiangxi Hongda Medical Equipment Group Ltd. specializes in manufacturing sterile medical devices for single use. Their products cover nine categories, such as infusion sets, blood transfusion equipment, injection equipment, puncture sets, examination and assistant supplies, anesthesia appliances, catheters, medical equipment, cardiovascular intervention, blood purification products, etc. It is a major supplier of sterile medical equipment for a lot of countries, such as the United States, Europe, Africa, the Middle East and the Southeast Asia. It is also one of biggest manufacturers to produce and process medical disposables, with nearly a quarter of the total market share in China alone. (Source: http://en.jxhd.cn/comcontent_detail.html)

- Henan Tuoren Medical Device Co., Ltd., founded in 2004, is a healthcare solutions provider, focusing on medical consumables and extending to electronic medical devices, surgery devices and biomedical materials. It is dedicated to designing, developing and distributing medical devices to its customers, covering 220 kinds of products with over 1880 specifications mainly in the field of anesthesia, pain management, nursing, diagnostics, surgery, hemodialysis and intervention. Its products have been sold to more than 70 countries and regions around the world, with international subsidiaries established in the United States and India. (Source: http://www.tuoren.com/en/index.php?s=/about/history.html)

- Allmed Medical Products Co., Ltd., founded in 1992, is the largest OEM (original equipment manufacturer) manufacturer and exporter of wound care products in China, providing a worldwide range of traditional wound care products, including gauze swabs, non-woven swabs, lap sponges, fluffy bandages, abdominal pads, non-stick pads, adhesive bandages, elastic bandages, medical kits and disposable drapes, etc. Compared with our products, their products are very limited. (Source: http://www.allmed-china.com/index.php?m=content&c=index&a=lists&catid=11)

- Jiangxi Sanxin Medtec Co., Ltd., founded in 1997, is a listed company in China, focusing on researching and developing, manufacturing and marketing of medical devices. It is the first listed company in the field of syringe and infusion. Their main products are "catheter tubing series," "blood purification series," "syringe series" and "infusion & transfusion series," totally four series products with over 30 types of more than 1000 specifications. Its products are sold both domestically and internationally, covering more than 30 provinces in China and more than 60 countries and regions nationwide. (Source: http://www.sanxin-med.com/category/Category/index/cid/295)

- Jiangxi 3L Products Group Co., Ltd., founded in 1990, combines the scientific research, production and marketing of single use medicinal macromolecular products and equipment, medical purification equipment sales, and maintenance and installation work into one. It established trade abroad with more than 20 countries and regions. It also has branch offices in Hong Kong, South Africa, Russia, etc. In the past few years, their surgical towels comprised of more than 90% of the domestic market share in China, and their combined sales have taken over half of the nationwide total product needs in the domestic market in China. (Source: http://www2.3l.com.cn/web/2.htm)

Our main competitors from other provinces and cities are Shandong Weigao Group, Jiangxi Hongda Group, Henan Tuoren Group, and Hubei Allmed Co., Ltd. These companies are our competitors as well as our partners. For example, Weigao Group in Shandong Province distributes disposable infusion pumps, medical kits, and other products produced by our Huodong subsidiary, while our Huadong subsidiary distributes the detained needle products of Weigao Group in our Yangzhou area; Tuoren Group distributes nitrile glove products of our Huadong subsidiary in Henan Province, while our Huadong subsidiary distributes Tuoren's medical guidewires and catheters in our Jiangsu Province. Another example is Hubei Allmed Co., Ltd., 80% of whose products are exported with 20% are domestically distributed (in comparison to our 80% domestic sales and 20% indirect exporting sales). The disposable stainless steel medical brushes it exports are exclusively supplied by our Yada subsidiary, so we regard company not only our domestic client, but also our competitor in the international market. Because of the huge market in China and in the world, there are tens of thousands of varieties of medical consumables. Not a single company in the world can dominate the entire market. While competing in the market, we more often cooperate with each other. Under the guidance of industry associations and local governments, we have formed an industry alliance to continuously exchange ideas with each other, discuss market development needs, and to build a common development platform. It should be noted that in the face of the sudden outbreak of the epidemic last year and this year, we shared information, supported each other with epidemic prevention materials, raw materials, and auxiliary materials, as well as production equipment, thus achieving win-win cooperation with fruitful outcomes.

A demand for one-stop service for medical consumables is an inevitable development in the medical consumables industry. There are several reasons why our company has achieved steady development over its more than 30 years history. One of the most important reasons is our one-stop service system, through which we can supply all disposable medical devices required by the client, combining products manufactured by us with products outsourced from others but passed through our quality control scrutiny. Through market research, we have learned that our competitors are also developing a one-stop service system and are in one of the following levels of progress: first, some companies have established a one-stop service system; second, some companies have established a one-stop service system, but their system is underperforming and needs improvement; and third, some companies are still undergoing development of a one-stop service system.

There are currently 385 manufacturers and distributors of medical consumables where the company is located in Touqiao Town, which is known as the "Hometown of Medical Consumables in China." As a top player in the region, the Company's revenues accounted for approximately 10% of the total revenues generated from all medical device manufactures in Touqiao Town. Our total sales in 2020 were more than RMB600 million (approximately ($89 million), with more than 10,000 product types. By comparison, our research indicates that the annual sales of the second- and third-ranking companies in Touqiao Town are just over RMB100 million, while the annual sales of the fourth- and fifth-ranking companies are in the range of RMB80 million to RMB90 million, with a lesser variety of product types. Since our production scale and number of product types far surpass those of other companies in Touqiao Town, we consider other local companies to be our partners more than our competitors. We supply each other's needs in terms of production, procurement, and distribution. At the same time, these local enterprises in Touqiao Town are not able to provide customers with the same one-stop service that we provide due to their limited scale and product types. The total output value of the top 20 companies in Touqiao Town, including our company, was about RMB2.3 billion in 2020. Our company's output value in 2020 was RMB610 million, accounting for about 26.5% of the total output value, while the other four next-largest companies in Touqiao Town had a total output value of about RMB400 million in 2020, accounting for 17.4% of the total output value.

Competitive Strengths

We are dedicated to serving our customers. We believe that the following strengths contribute to our success and are the differentiating factors that set us apart from our peers:

- ***Cost-effective methods to address customers' significant needs with a variety of products.*** As of the date of this report, we have a total of 1063 products in our product portfolio covering all Class I, II, and III disposable medical devices, including 937 products for domestic sales and 126 products for overseas sales. Through sales of different products to our customers via our one-stop service, we are able to cost-effectively address our client's needs.

- ***Massive distribution network of clients, distributors, and suppliers.*** Through both direct sales and our massive distribution network, our products are sold to hospitals, pharmacies and medical institutions both domestically and internationally. As of the date of this report, we have 81 employees in our sales department and 5,000 independent sales agents, 3,004 distributors for domestic sales and 324 exporting distributors for overseas sales. We not only have accumulated a substantial domestic customer base and forged strong relationships with these customers, but also established good long-term cooperative relationships with well-known foreign medical equipment brand companies, which extends our reach world-wide. We believe that these customers will continue to be a source of business as well as a good referral source to new customers.

- ***Geographical advantages allow us to provide one-stop service to our customers at reduced cost.*** Hospitals and other medical institutions normally have lists of over a hundred or even a thousand of different kinds of disposable medical devices which they must procure on a regular basis. Our PRC operating subsidiaries and primary operations are located in Touqiao Town, Yangzhou City, Jiangsu Province, one of the four medical device centers in PRC. Dubbed the "Hometown of Medical Devices & Consumables in China," Touqiao Town hosts hundreds of disposable medical device manufacturers manufacturing all different kinds of products. In addition to our own products, we are qualified to distribute products sourced from other manufacturers. As a result, our clients are able to receive all required products by placing just a single order with us. When we receive an order from our hospital clients or distributors, we are able to quickly fulfill the order by including our own branded products and qualified products sourced from other manufacturers in Touqiao Town. There are also large numbers of medical device professionals, including research and development, or "R&D," and technology professionals, and thousands of independent sales agents based near our primary operations. We are therefore able to procure high quality raw materials and products of other brands at a comparatively low price within a short period of time and to obtain sufficient labor and support to our one-stop service and manufacturing.

- ***Economies of scale and automation provide significant cost advantages.*** The scale of our production is regional-leading within Yangtze River Delta region of China. The disposable medical devices we manufacture and sell are mainly low value-added products, which, however, are largely consumed and in huge demand every day in hospitals, medical institutions, and other health related industry entities. Through scaled production, we are able to increase our profits margin. In the procurement process, the production scale reduces our procurement costs and mitigate the impact of raw material price fluctuations. In the manufacturing process, we retrofitted equipment and introduced automation to improve production efficiency. At present, we have 12 purification plants covering a total area of approximately 110,352 square feet (10,252 square meters).

- ***Leading competitive position maintained by high quality standard systems.*** Quality and safety are always our core value. Applying information acquired during our long-term business transactions with major medical institutions across China, we have developed a sophisticated quality management system, as well as a strict and effective internal control standard system. All of our products, either self-manufactured or sourced, fall within our quality control system subject to our quality inspection before delivery (See the section entitled "Quality Control" in Business).

- ***Market-driven research and development allow for continual improvement and long-term client loyalty.*** As of the date of this report, we have an R&D team of 78 people, accounting for 12.46% of our total employees. For the fiscal year ended December 31, 2022, we have invested a total of $2,962,904 in the products and technologies R&D. For the fiscal years ended December 31, 2021 and 2020, we have invested a total of $2,725,014 and $2,492,059 in the products and technologies R&D. We adhere to a market-oriented R&D approach and actively cooperate with universities, hospitals, medical institutions, distributors and independent sales agents in sorting out our R&D orientation based on the real market demand. We continuously upgrade and improve our products and technologies to better suit our customers.

- ***Visionary and experienced management team***
  Building a trusted brand and always doing the right thing for people has been at the heart of our founding management team since day one. Our company culture, strategic vision and operational execution are driven by our visionary founder, Yongjun Liu. Mr. Liu is a successful entrepreneur who has been engaged in the medical device industry for more than 40 years and has accumulated extensive experiences and led his businesses to make remarkable achievements. He has been awarded as Excellent Entrepreneur, Honest Entrepreneur Representative and Medical Device Industry Representative on multiple occasions. At the same time, he is keen on public welfare undertakings. He has also sponsored a lot of splendid undertakings such as road reconstruction in towns and villages, donations to the Red Cross Society, reconstruction of nursing homes, poverty alleviation and aid for students. Our company culture mirrors our founder's mission to empower and serve those who serve others.

Quality Control

All of our products, either self-manufactured or sourced, fall within our quality control system subject to our quality inspection before delivery. For sourced products, they must first be shipped to us for quality inspection, upon passing inspection, be packaged, labeled and shipped to our customers.

Medical device and equipment are medical products directly applied to the human body, which is closely related to the life and health of users. Quality and safety are always our core value. Reliable, safe and stable product quality is an important driving factor for maintaining market competitiveness. Through long-term business dealings with major hospitals and medical institutions across China, we believe that we have developed a sophisticated quality control management system as well as a strict and effective internal control system in accordance with the requirements of Chinese laws and regulations.

We prioritize product quality management and are committed to strengthening the professional ethics and cultivating quality consciousness of our employees, forming a strict quality management system, which we believe is in line with international standards.

Our rigorous quality control management programs have earned us a number of quality-related manufacturing designations. Our manufacturing facilities are ISO 13485 compliant with ISO 13485:2016 edition certification achieved in 2020. In 2018, we achieved compliance with European Union's CE certification, allowing certain of our products (such as Disposable Amniotic Membrane Perforators, Disposable Medical Suction Connecting Tubes and Disposable Gynecologic Samplers) to be CE marked. In April 2020, we renewed registration of certain products with the FDA, including ID bracelet, surgical tapes, elastic, adhesive bandages, etc., allowing our products to enter U.S. market. We have more than 60 categories of products passed the quality system inspections administered by the China Food and Drug Administration and local authorities in Yangzhou City.

We have annual quality targets, which are distributed to our employees and all departments annually. We conduct monthly follow-ups and quarterly evaluations on execution of the plans held to ensure that the annual quality targets are met.

However, despite our quality control management system, we cannot eliminate all risks of errors, defects or failures. We may fail to detect or cure defects as a result of a number of factors, many of which are outside our control, including:

- technical or mechanical malfunctions in the production process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- defective raw materials or equipment.

Failure to detect quality defects in our products could result in patient injury, customer dissatisfaction, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenue and profitability.

In 2018, our PRC subsidiaries Jiangsu Yada and Jiangsu Huadong got fined of immaterial amount for noncompliance with the local laws and regulations. Upon receipt of the fine notices, we promptly reacted to the comments from the related local government, rectified the noncompliance situation, recalled all noncompliance products and paid the fines in full. As a result, we took some measures to avoid future noncompliance.

Specific rectification measures and the impacts on our products and business are as follows:

No.	Penalty decision	Misconduct for penalized	Regulatory measures after rectification	Effect on products/business
1	(Yangzhou) Shi Yao Jian Xie Fa [2017] No. 48 / (Yangzhou) Shi Yao Jian Xie Fa [2018] No. 23	Medical surgical film does not label the texture of the transparent plastic film/ providing fake registration product criterion to the Food and Drug regulatory authority that supervises and inspects products	Canceling registration certificates and stopping producing such related products	The Company has canceled the relevant registration certificates and no longer produced such products. Because the output of these products is minor, which occupies an extremely low proportion of the Company's total products, terminating the production of this product will not exert any adverse effect on the Company's business.
2	(Yangzhou) Shi Yao Jian Xie Fa [2017] No. 46	Production of inspection gloves that fail to meet the compulsory standards [model specification: 7.5] (Production date of glossy powder: 20170108) (The reason for the insufficient tension is that the rubber supplier has not followed the specifications standards during production)	Enhancing the random inspection of the supplier's production specification standards when accepting outsourced materials, as well as promoting the proportion of random inspections	Such administrative penalty has not adversely affected products and the Company's business.
3	(Yangzhou) Shi Yao Jian Xie Fa [2018] No. 16	"ultraviolet absorbance" test of disposable infusion pumps has failed (The main reason that caused the product's UV absorbance to exceed the standard is the secondary vulcanization time and vulcanization temperature of the liquid storage bag has not met the specified requirements. The liquid storage bag is an outsourcing material, and the original supplier does not strictly follow its production process specifications during production, which shortens the secondary vulcanization time and vulcanization temperature, causing UV absorbance to exceed the standard.)	1. Switch to another supplier of the liquid storage bag; 2. Improve the internal control standard requirements for the incoming inspection of liquid storage bags (the ultraviolet absorbance index of the incoming inspection liquid storage bag is ≤ 0.2)	Such administrative penalty has not adversely affected products and the Company's business.

For the fiscal year of 2022 and as of the date of this report, we are not aware of any investigations, prosecutions, disputes, claims or other proceedings in respect of quality issues, nor has the Company been punished or can foresee any punishment to be made by any related government authorities of the PRC.

Class I, II, and III Medical Device Approval Process in China

"Class I" medical devices in China refers to sanitary and civilian products with extremely low risk, which do not need to be disinfected. To record this type of product in the official catalogue, a recordation application must be submitted on the website of the National Medical Products Administration. The application must clarify relevant information about product standard, the scope of use, production technologies, and instructions for the use of material. The device may then be produced and distributed after obtaining the online approval of the National Medical Products Administration. The application and approval process for Class I devices is as follows:

Schedule 1 Flow Chart of the Application Procedures for Recordation of the Medical Devices of Class I

(statutory time limit: on-the-spot conclusion)

[Chart derived from regulations on the supervision and administration of medical devices (Order No. 650 of the State Council of the PRC) and the Measures for the supervision and administration of the operation of medical devices (Order No. 8 of the State Food and Drug Administration)].

“Class II” and “Class III” medical devices in China refer to medical-grade products with higher risk. The application procedures for recordation of these two types of products in China are as follows: First, the products are submitted for inspection with various materials. After the submitted materials are reviewed by the experts to their satisfaction, the National Medical Products Administration will organize a team of experts to visit the factory for on-site inspection and acceptance. After passing the on-site acceptance, the products with higher risk are required to be clinically tested. Only after the clinical report and other application documents are submitted to the National Medical Products Administration, which approves these materials and issues the product registration certificate, shall the enterprise be allowed to produce and distribute the product. The application and approval process for Class II and III devices is as follows:

[Chart derived from regulations on the supervision and administration of medical devices (Order No. 650 of the State Council of the PRC) and the Measures for the supervision and administration of the operation of medical devices (Order No. 8 of the State Food and Drug Administration)].

The chart below summarizes the classification, approval dates, and current approval terms of our top 20 products:

No.	Product Name	Remarks	Date of approval	Term of validity	Class
1	Disposable ID bracelet	By Yada, CE certified	2020-12-17	2023-12-16	Class II
2	Disposable medical brush				Class II
3	Masks	By Huadong	2021-2-26	2026-2-25	Class II
4	Disposable woman's examination kits	By Huadong	2021-2-25	2026-2-24	Class II
5	Medical Brush	Source from other (No registration certificate is required)	Class II		
6	Medical kit	Source from other (No registration certificate is required)	Class II		
7	Medical sterile dressing surgical kits	By Yada, CE certified	2020-12-17	2023-12-16	Class II
8	Medical catheter	Source from other (No registration certificate is required)	Class II		
9	Uterine tissue suction tube	By Yada, CE certified	2020-12-17	2023-12-16	Class II
10	Low-density polyethylene (LDPE) bottles for eye drops	By Huada, Long term	Class I		
11	High-density polyethylene (HDPE) bottles for tablets	By Huada, Long term	Class I		
12	Disposable women's examination kits	Source from other (No registration certificate is required)	Class II		
13	Disposable Gynecological sampler	By Yada, CE certified	2020-12-17	2023-12-16	Class II
14	Disposable medical brush (type B1)	By Yada, CE certified	2020-12-17	2023-12-16	Class II
15	Disposable anal bag	By Yada, CE certified	2020-12-17	2023-12-16	Class II
16	Inspection gloves	By Yada	2016-2-29	Long term	Class I
17	Disposable humidified nasal oxygen tube	By Huadong	2021-1-27	2026-1-26	Class II
18	Disposable suction connecting tube	By Huadong	2021-3-9	2026-3-8	Class II
19	Medical dressing	By Huadong	2018-4-18	2023-4-17	Class II
20	Electronic pump	By Huadong	2021-3-9	2026-3-8	Class III

Competitive Challenges

- ***Our production capacity for certain pandemic prevention products is limited.*** Our existing production capacity for certain products, consisting primarily of some pandemic prevention-related products, is unable to meet the current market demand due to limitations on our funding, production equipment, and facilities. As a result, our ability to expand our market share in this area is limited.

- ***To date, limited access to capital has slowed our ability to gain additional market share.*** Our various product lines have developed rapidly and are competitive in the market. However, expansion of our production capacity, deepening of our marketing network, and improvement of our research and development efforts require sufficient capital investment. To date, lack of access to sufficient capital has limited some projects with development potential and has tempered our further expansion of market share. The Company needs more capital to expand its operations.

- ***We sell primarily low value-added products, which limits our sales margins.*** The Company currently primarily manufactures and sells Class I and Class II medical products, with a lesser proportion of Class III products. The medical device industry is highly competitive, especially in respect of low value-added medical devices, which has low entry requirements subject to rapid change and significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. As a result, we may find it difficult to compete with companies commercializing high-end products and enjoying a higher profit margins per-product.

Manufacturing

Our production is comprised of both in-house manufacturing and outsourcing to third parties. Except for purchases according to the requirement of bid clients, all third party manufactures shall ship products to us for our inspection first, and upon passing our inspection, we will label and assemble, and then ship them to clients per orders.

In-house Manufacturing

All of our in-house production is located at our facilities in Yangzhou, Jiangsu Province, PRC. At those facilities, we produce products and stock inventory of raw materials, components and finished goods at our facilities pursuant to the market demand, orders we receive or plan to receive, our production plan and capacity, procurement information from our direct sales force and our distributors. Our in-house per-order production model is as follows:

Due to the nature of the products, all products must be produced in the dust-free purification workshops and must be sterilized. This production process is subject to continuous review and monitoring by the quality control team to ensure that finished products are of the highest quality and meet customer requirements and ISO 13485 medical device quality management systems standard.

In order to the maintain product safety and a high standard of product quality, we implement a strict set of quality control policies and inspection protocols. These policies and protocols are enforced by our quality control team, senior management and officers along every step of the production to post-production process.

*Outsourcin*g

Our outsourcing of products, which to some extent expands our production capacity, are produced by third party manufacturers by either 1) using qualified raw material suppliers designated by us and completing the production in accordance with our standards, or 2) using their own selection of raw materials and production standards in line with our quality control requirements.

Given our unique geographical location, we are able to procure qualified raw materials, and locate qualified third party manufacturers and suppliers locally at a cost-effective way such as lower price and save of transportation costs in a shorten period, thus realizing scale production, reducing our production costs and increasing profit margin. By outsourcing some semi-finished product processing to the local consigned manufacturers in Touqiao Town, we not only expand our production capacity and improve our production efficiency, but also reduce production costs while meeting clients' demands for products of various specifications.

Environmental

Due to the nature of the Company's products, the Company's PRC subsidiaries do not generate industrial wastewater and wastes, the wastewater they generate is sanitary wastewater which can be disposed directly into municipal pipelines. The generated corner wastes shall be cleaned and collected by the cleaning personnel on time, and then transported to the municipal garbage disposal site for treatment by the local sanitation department. Solid wastes generated during operation shall be collected and sent to relevant manufacturers for recycling. If new products are developed in the future and environmental measures are needed according to law, the Company will take corresponding environmental protection measures according to relevant laws and regulations. The waste discharge fees for fiscal years of 2022, 2021, and 2020 were $4,384, $4,890, and $5,009, respectively, which has been paid in full.

The Company and its subsidiaries passed the environmental inspection and evaluation by the Environmental Protection Bureau of Yangzhou Guangling District in 2020, which determined that no waste, hazardous substances or wastewater were produced during manufacturing.

As of the date of this report, our waste discharge is in compliance with the local laws and regulations and we are not aware of any warning, investigations, prosecutions, disputes, claims or other proceedings in respect of environmental protection, nor have we been punished or can foresee any punishment to be made by any government authorities of the PRC.

Intellectual Property

Our business is dependent on a combination of trademarks, patents, copy rights, domain names, trade names, trade secrets and other proprietary rights in order to protect our intellectual property rights. As of the date of this report, we have two (2) registered trademark, twenty-seven (27) registered patents and two (2) copyrights in the PRC.

Trademarks

Set forth below is a detailed description of our registered trademarks:

Country	Trademark	Trademark Registration No.	Trademark Name	Trademark Registration Date	Trademark Classes	Trademark Owner	Trademark Term	Trademark Status
China		19576090	Hu Jun	08/28/2017	30	Jiangsu Yada	08/28/2017 to 08/27/2027	Registered
China		1415306	Yada	06/28/2000	10	Jiangsu Yada	06/28/2020 to 6/27/2030	Registered
China		1421255	Yada	07/14/2000	6	Jiangsu Yada	07/14/2020 to 07/13/2030	Registered

Patents

China's patent law stipulates that there are three types of patent protection: invention patent, utility model patent and design patent.

- A patent for invention refers to a new technical solution for a product, a method or an improvement thereof.
- Utility model patent refers to a new technical solution suitable for practical use, which is proposed for the shape, structure or combination of the product.
- Design patent refers to the new design of product shape, pattern, color or their combination, which is aesthetic and suitable for industrial application.

Set forth below is a detailed description of our registered patents:

Country	Patent No.	Patent Name	Patent Publication Date	Patent Type	Patent Validity Period	Patent Status
China	ZL201310537304.7	Wound marginal cell crawling promoting type temperature control swell-shrink type drainage tube	09/09/2015	Invention	20 years from the application date (11/03/2013)	Renewed and effective
China	ZL201420092814.8	Nano-crystalline cellulose dressing for treating extensive burns	2/25/2015	Utility model	10 years from the application date (3/3/2014)	Registered and effective
China	ZL201821229644.8	Bone mineral density instrument with good anti-falling performance	7/5/2019	Utility model	10 years from the application date (8/1/2018)	Registered and effective
China	ZL2019 2235101 2.X	Novel device for gynecological diagnosis and treatment	10/16/2020	Utility model	10 years from the application date (12/24/2019)	Registered and effective
China	ZL202020002206.9	Joint fixation frame for orthopedic surgery	10/23/2020	Utility model	10 years from the application date (01/01/2020)	Registered and effective
China	ZL202020017703.6	Wound debridement device for emergency care	10/16/2020	Utility model	10 years from the application date (01/06/2020)	Registered and effective

Country	Patent No.	Patent Name	Patent Publication Date	Patent Type	Patent Validity Period	Patent Status
China	ZL2013105373 27.8	Interrupted thread clearance hole wall type injection needle	11/4/2015	Invention	20 years from the application date (11/3/2013)	Registered and effective
China	ZL201922473496.5	Sputum suction tube preventing respiratory mucosa from being damaged	10/20/2020	Utility model	10 years from the application date (12/31/2019)	Registered and effective
China	ZL202020129072.7	High-flow oxygen supply mask drainage and medicine delivery mechanism in the department of respiratory medicine	10/20/2020	Utility model	10 years from the application date (01/20/2020)	Registered and effective
China	ZL201922332612.1	Uterine cavity sampler for gynecological reproductive clinics	10/23/2020	Utility model	10 years from the application date (12/23/2019)	Registered and effective
China	ZL201922412254.5	Disposable intubate package	10/30/2020	Utility model	10 years from the application date (12/28/2019)	Registered and effective
China	ZL201921757111.1	Painless anesthetic needle	11/3/2020	Utility model	10 years from the application date (10/19/2019)	Registered and effective
China	ZL201910037322.6	Neurological rehabilitation adjuvant therapy stimulation device	10/23/2020	Invention	20 years from the application date (01/15/2019)	Registered and effective
China	ZL202023332943.4	Glucometer	10/15/2021	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023296047.7	Portable blood glucose meter	1/7/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023343934.5	Bone density tester	1/14/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023296027.X	Rotatable densitometer	1/18/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023290045.7	Surgical stapler	1/18/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023295973.2	New cutting stapler	3/29/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023313858.3	New medical mask	1/17/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023295982.1	New warm and anti-fog masks	3/29/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective

Country	Patent No.	Patent Name	Patent Publication Date	Patent Type	Patent Validity Period	Patent Status
China	ZL202023296016.1	Wrist blood pressure meter	3/29/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023342335.1	Portable blood pressure meter	1/14/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023313904.X	Medical identification wristband	3/29/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	ZL202023342334.7	Corrective device to prevent myopia	1/18/2022	Utility model	10 years from the application date (12/31/2020)	Registered and effective
China	2018212296448	Bone densitometer with good anti-fall performance	7/26/2019	Utility model	10 years from the application date (8/1/2018)	Registered and effective
China	2014200928148	Nanocellulose dressing for extensive burns	2/25/2015	Utility model	10 years from the application date (3/3/2014)	Registered and effective

Our currently registered patents do not relate to our top 20 products, which are mature products. Instead, our registered patents represent the phased achievements of our R&D department, which will serve as the basis for future research and the planned development of new products.

Currently, we have 27 registered and effective patents, and we have not signed any royalty or licensing agreements with any third parties with respect to these patents. Currently, however, we are working under a collaboration agreement to develop and register a patented product for production and sale. The patent relates to a tracheal tube kit capable of pulverization and dosing by a tube wall fan spraying concurrently, and it is a utility model patent issued in China with a validity period of ten years from May 29, 2019. A utility model patent is issued for a new technical scheme suitable for practical use based on the shape, structure or combination of the products used. Moreover, to be suitable for a utility model patent, an invention must possess novelty, creativity and practicability. We are authorized by the patent owner to develop a new use for his patent and to file a medical device registration certificate for the developed product. Under our agreement with the patent owner, once the product is in production and sales, we will distribute 25% of the profit after tax to him. Under the agreement, the patent owner has the right to request an accounting of profits at his own expense. If the patent owner wishes to transfer the patent in the future, he can only transfer it to us. For this collaboration agreement, we have completed the development of the new use of the patented product, and we are in the process of applying for medical device registration certificate. Because the new product has not been put into production and has not generated any sales yet, we have not distributed any profit to the patent owner and no other fees have been paid or received under the agreement. The collaboration agreement and the profit-sharing arrangement are for a perpetual term. The collaboration agreement may be terminated, however, in the event that we are unable to provide an accurate accounting of profits for the product to the patent owner. In that case, all rights to the patent may be returned to the patent owner and we will be liable for damages in the amount of an additional 10% of net profits received from the product.

Copyrights

Set forth below is a detailed description of our registered copyrights:

Country	Copyright No.	Copyright Name	Copyright Publication Date	Copyright Type	Copyright Application Date	Copyright Status
China	2019SR0829585	Self-service printing terminal control system software of image diagnostic film (V1.0)	8/9/2019	software copyright	6/13/2019	Registered and effective
China	2019SR0813645	Intelligent Medical film image printing output system software (V1.0)	8/6/2019	software copyright	6/20/2019	Registered and effective

Insurance

We maintain Group Life Insurance for some of our high-risk employees, such as electricians, plumbers and tooling operators. We also provide social security insurance including pension, medical insurance, unemployment insurance, maternity insurance, on-the-job injury insurance and housing fund plans through a PRC government-mandated benefit contribution plan for our employees. We do not carry any key-man life insurance, product liability and professional liability insurance. Even if we purchase these kinds of insurance, the insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. We have not purchased any property insurance or business interruption insurance. We have determined that the costs of insuring for related risks and the difficulties associated with acquiring such insurance on commercially reasonable terms make it impractical. We consider our insurance coverage to be sufficient for our business operations in China.

Legal Proceedings

We may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. Litigation or any other legal or administrative proceeding, regardless of the outcome, is likely to result in substantial cost and diversion of our resources, including our management's time and attention.

With the exception of the following proceedings, we are currently not a party to any material legal or administrative proceedings:

- Case No. CGC-22-598030, Macias, Gini & O'Connell LLP vs. Meihua International Medical Technologies Co., Ltd., filed April 2, 2022 in the Superior Court of California, County of San Francisco. This is an action filed by a former accounting firm for the collection of allegedly past-due professional fees. We believe the action to be without merit, have responded to the complaint and are defending this action, accordingly.

REGULATIONS

We operate our business in the PRC under a legal regime consisting of the National People's Congress, which is the country's highest legislative body, the State Council, which is the highest authority of the executive branch of the PRC central government, and several ministries and agencies under its authority, including the State Administration of Foreign Exchange, or SAFE, the Ministry of Commerce, or MOFCOM, the National Development and Reform Commission, or NDRC, the State Administration for Market Regulation, or SAMR, formerly known as the State Administration for Industry and Commerce, or SAIC, the Ministry of Civil Affairs, or MCA, and their respective authorized local counterparts.

This section sets forth a summary of the most significant rules and regulations that affect our business activities in the PRC.

Regulation Relating to Foreign Investment

All limited liability companies incorporated and operating in the PRC are governed by the *Company Law of the People's Republic of China*, or the Company Law, which was amended and promulgated by the Standing Committee of the National People's Congress on October 26, 2018. However, on December 24, 2021, the Standing Committee of the National People's Congress issued the Company Law of the People's Republic of China (Draft for Comments) (the "Revised Company Law"), which is now open for public comments. The Revised Company Law further stipulates the establishment and withdrawal of the company, the organizational structure and the capital system of the company, and strengthens the responsibilities of shareholders and management personnel and Corporate Social Responsibility. Foreign invested projects must also comply with the Company Law, with exceptions as specified in foreign investment laws.

The Foreign Investment Law of the People's Republic of China (the "Foreign Investment Law") was adopted by the second meeting of the 13th National People's Congress on March 15, 2019, which became effective on January 1, 2020. On December 26, 2019, the State Council promulgated Regulation for Implementing the Foreign Investment Law of the People's Republic of China (the "Regulation"), which became effective on January 1, 2020.

The Foreign Investment Law and the Regulation apply the administrative system of pre-establishment national treatment plus negative list to foreign investment and clarify the state shall develop a catalogue of industries for encouraging foreign investment to specify the industries, fields, and regions where foreign investors are encouraged and directed to invest. The MOFCOM and NDRC promulgated the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021 Version) (the "2021 Negative List") on December 27, 2021, which became effective on January 1, 2022. The 2021 Negative List replaced the Special Administrative Measures for the Access of Foreign Investment (2020 Version) and serves as the main basis for management and guidance for the MOFCOM to manage and supervise foreign investments. The restricted and prohibited industry categories have shareholding requirements as prescribed in the 2021 Negative List. Those industries not set out on the 2021 Negative List shall be classified as industries permitted for foreign investment. None of our businesses are on the 2021 Negative List, nor on the 2020 Negative List. Therefore, the Company is able to conduct its business through its wholly owned PRC Subsidiaries without being subject to restrictions imposed by the foreign investment laws and regulations of the PRC. In addition, the version of the Catalogue of Industries for Encouraged Foreign Investment currently in force was amended in 2022 and became effective on January 1, 2023, which replaced the Catalogue of Industries for Encouraged Foreign Investment (2020 version).

Regulation Relating to Wholly Foreign-owned Enterprises

The abovementioned Company Law of the People's Republic of China provides that companies established in the PRC may take the form of company of limited liability or company limited by shares. Each company has the status of a legal person and owns its assets itself. Assets of a company may be used in full for the company's liability. The Company Law applies to foreign-invested companies unless relevant laws provide otherwise.

The Foreign Investment Law replaced Law of the People's Republic of China on Wholly Foreign-owned Enterprises. It stipulates that the PRC implements a system of pre-establishment national treatment plus negative list for the administration of foreign investment. Foreign investors are not allowed to invest in fields or sectors prohibited in the market access negative list for foreign investment. Foreign investors that intend to invest in the fields subject to access restrictions stipulated in market access negative list for foreign investment shall satisfy the conditions stipulated in such negative list. The PRC policies supporting enterprise development are equally applicable to foreign-invested enterprises. The PRC does not impose expropriation on foreign investment. Under special circumstances, if it requires imposing expropriation on foreign investment due to the need of public interest, expropriation shall be imposed according to legal procedures, and the foreign-invested enterprises concerned shall receive fair and reasonable compensation. Foreign-invested enterprises can raise funds through public issuance of stocks, corporate bonds and other securities in accordance with the law. Overall, The Foreign Investment Law establishes the clear principle of applying national treatment to FIEs except those engaged in industries on the 2020 Negative List. Since our current and planned business is not on the 2021 Negative List, to the best of our knowledge, it will not create any material adverse effect to our Company's business.

Regulations Relating to Intellectual Property

Copyright

China has adopted comprehensive legislation governing intellectual property rights, including trademarks and copyrights. China is a signatory to the primary international conventions on intellectual property rights and has been a member of the Agreement on Trade Related Aspects of Intellectual Property Rights since its accession to the WTO in December 2001.

In September 1990, the SCNPC promulgated the Copyright Law of the People's Republic of China, effective in June 1991 and amended in 2001, 2010 and 2020 respectively. The amended Copyright Law extends copyright protection to internet activities, products disseminated over the internet and software products. In addition, there is a voluntary registration system administered by the Copyright Protection Centre of China.

In order to further implement the Computer Software Protection Regulations, promulgated by the State Council in December 2001 and amended in 2011 and 2013 respectively, the National Copyright Administration issued Computer Software Copyright Registration Procedures in February 2002, which specify detailed procedures and requirements with respect to the registration of software copyrights.

Trademark

According to the Trademark Law of the People's Republic of China, promulgated by the SCNPC in August 1982, and amended in 1993, 2001, 2013 and 2019 respectively, the Trademark Office of China National Intellectual Property Administration is responsible for the registration and administration of trademarks and is also responsible for resolving trademark disputes in China. Registered trademarks are valid for ten years from the date the registration is approved. A registrant may apply to renew a registration within twelve months before the expiration date of the registration. If the registrant fails to apply in a timely manner, a grace period of six additional months may be granted. If the registrant fails to apply before the grace period expires, the registered trademark shall be deregistered. Renewed registrations are valid for ten years. In April 2014, the State Council issued the revised Implementation of the Trademark Law, which specified the requirements of applying for trademark registration and review.

Patent

According to the Patent Law of the People's Republic of China promulgated by the SCNPC in 1984 and amended in 1992, 2000, 2008 and 2020, respectively, a patentable invention or a utility model must meet three criteria: novelty, inventiveness and practicability. A patent is valid for a twenty-year term for an invention and a ten-year term for a utility model or design, starting from the application date.

Domain Names

In May 2012, the China Internet Network Information Center issued the Implementing Rules for Domain Name Registration setting forth the detailed rules for registration of domain names. In August 2017, China's Ministry of Industry and Information Technology promulgated the Administrative Measures on Internet Domain Names, or the Domain Name Measures. The Domain Name Measures regulate the registration of domain names, such as the top-level domain name ".cn".

Regulations on Offshore Parent Holding Companies' Direct Investment in and Loans to Their PRC Subsidiaries

An offshore company may invest equity in a PRC company, which will become the PRC subsidiary of the offshore holding company after investment. Such equity investment is subject to a series of laws and regulations generally applicable to any foreign-invested enterprise in China, all as amended from time to time, and their respective implementing rules; the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors; and the Notice of the State Administration on Foreign Exchange on Further Improving and Adjusting Foreign Exchange Administration Policies for Direct Investment. Under the aforesaid laws and regulations, the increase of the registered capital of a foreign-invested enterprise is subject to the prior approval by the original approval authority of its establishment. In addition, the increase of registered capital and total investment amount shall both be registered with SAIC and SAFE. Shareholder loans made by offshore parent holding companies to their PRC subsidiaries are regarded as foreign debts in China for regulatory purpose, which is subject to a number of PRC laws and regulations, including the PRC Foreign Exchange Administration Regulations, the Interim Measures on Administration on Foreign Debts, the Tentative Provisions on the Statistics Monitoring of Foreign Debts and its implementation rules, and the Administration Rules on the Settlement, Sale and Payment of Foreign Exchange. Under these regulations, the shareholder loans made by offshore parent holding companies to their PRC subsidiaries shall be registered with SAFE.

Regulations Relating to Foreign Exchange

Pursuant to the Foreign Exchange Administration Regulations, as amended in August 2008, the RMB is freely convertible for current account items, including the distribution of dividends, interest payments, trade and service-related foreign exchange transactions, but not for capital account items, such as direct investments, loans, repatriation of investments and investments in securities outside the PRC, unless SAFE's prior approval is obtained and prior registration with SAFE is made. In May 2013 SAFE promulgated the Circular of the SAFE on Printing and Distributing the Administrative Provision on Foreign Exchange in Domestic Direct Investment by Foreign Investors and Relevant Supporting Documents which provides for and simplifies the operational steps and regulations on foreign exchange matters related to direct investment by foreign investors, including foreign exchange registration, account opening and use, receipt and payment of funds, and settlement and sales of foreign exchange.

Pursuant to the Circular on Relevant Issues concerning Foreign Exchange Administration of Overseas Investment and Financing and Return Investments Conducted by Domestic Residents through Overseas Special Purpose Vehicles or the SAFE Circular 37, promulgated by SAFE and which became effective on July 4, 2014, (a) a PRC resident shall register with the local SAFE branch before he or she contributes assets or equity interests in an overseas special purpose vehicle, or Overseas Special Purpose Vehicles (SPV), that is directly established or controlled by the PRC Resident for the purpose of conducting investment or financing; and (b) following the initial registration, the PRC Resident is also required to register with the local SAFE branch for any major change, in respect of the Overseas SPV, including, among other things, a change of the Overseas SPV's PRC Resident shareholder (s), name of the Overseas SPV, term of operation, or any increase or reduction of the Overseas SPV's registered capital, share transfer or swap, and merger or division. Pursuant to SAFE Circular 37, failure to comply with these registration procedures may result in penalties.

Pursuant to the Circular of the State Administration of Foreign Exchange on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies, or the SAFE Notice 13, which was promulgated on February 13, 2015 and with effect from June 1, 2015, the foreign exchange registration under domestic direct investment and the foreign exchange registration under overseas direct investment is directly reviewed and handled by banks in accordance with the SAFE Notice 13, and the SAFE and its branches shall perform indirect regulation over the foreign exchange registration via banks.

Regulations Relating to Dividend Distributions

According to the PRC Company Law and Foreign Investment Law, each of our PRC subsidiaries, as a foreign invested enterprise, or FIE, are required to draw 10% of its after-tax profits each year, if any, to fund a common reserve, which may stop drawing its after-tax profits if the aggregate balance of the common reserve has already accounted for over 50% of its registered capital. These reserves are not distributable as cash dividends. Furthermore, under the EIT Law, which became effective in January 2008, the maximum tax rate for the withholding tax imposed on dividend payments from PRC foreign invested companies to their overseas investors that are not regarded as "resident" for tax purposes is 20%. The rate was reduced to 10% under the Implementing Regulations for the EIT Law issued by the State Council. However, a lower withholding tax rate might be applied if there is a tax treaty between China and the jurisdiction of the foreign holding companies, such as tax rate of 5% in the case of Hong Kong companies that holds at least 25% of the equity interests in the foreign-invested enterprise, and certain requirements specified by PRC tax authorities are satisfied.

Regulations Relating to Overseas Listings

On July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the "Opinions on Severely Cracking Down on Illegal Securities Activities According to Law," or the Opinions. The Opinions emphasized the need to strengthen the administration over illegal securities activities, and the need to strengthen the supervision over overseas listings by Chinese companies. Effective measures, such as promoting the construction of relevant regulatory systems will be taken to deal with the risks and incidents of China-concept overseas listed companies, and cybersecurity and data privacy protection requirements and similar matters.

On December 24, 2021, the China Securities Regulatory Commission, or the CSRC, issued Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (the "Administration Provisions"), and the Measures for the Overseas Issuance of Securities and Listing Record-Filings by Domestic Enterprises (Draft for Comments) (the "Measures"), which were published for public comments only, for which the comment period expired on January 23, 2022.

The Administration Provisions and Measures (collectively, the "Draft Rules Regarding Overseas Listing") for overseas listings lay out specific requirements for filing documents and include unified regulation management, strengthening regulatory coordination, and cross-border regulatory cooperation. Domestic companies seeking to list abroad must carry out relevant security screening procedures if their businesses involve such supervision. Companies endangering national security are among those off-limits for overseas listings.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines, which came into effect on March 31, 2023. The Trial Measures and its supporting guidelines, reiterate the basic principles of the Draft Rules Regarding Overseas Listing and impose substantially the same requirements for the overseas securities offering and listing by domestic enterprises. Pursuant to the Trial Measures, domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete filing procedures with the CSRC pursuant to the requirements of the Trial Measures within three working days following its submission of initial public offerings or listing application. If a domestic company fails to complete the required filing procedures or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as orders to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

According to the Notice on the Administrative Arrangements for the Filing of the Overseas Securities Offering and Listing by Domestic Companies from the CSRC, or the CSRC Notice, which was promulgated on February 17, 2023 and became effective on the same day, the domestic companies that have already been listed overseas before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers (the "Existing Issuers"). Existing Issuers are not required to complete the filing procedures immediately, and they shall be required to file with the CSRC for any subsequent offerings. Further, according to the CSRC Notice, domestic company obtained approval from overseas regulatory authorities or securities exchanges (for example, the effectiveness of a registration statement for offering and listing in the U.S. has been approved) for their indirect overseas offering and listing prior March 31, 2023 but have not yet completed their indirect overseas issuance and listing, are granted a six-month transition period from March 31, 2023 to September 30, 2023. Those issuers that complete their indirect overseas offering and listing within such six-month period are deemed as Existing Issuers and are not required to file with the CSRC for their indirect overseas offerings and listings. Within such six-month transition period, however, if such domestic companies fail to complete their indirect overseas issuance and listing, they shall complete the filing procedures with the CSRC.

The Opinions, the Trial Measures and any related implementing rules to be enacted may subject us to additional compliance requirements in the future financial activities. See "Risk Factors - Risks Relating to Doing Business in the PRC - The Chinese governmental and regulatory interference could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless."

In August 2006, six PRC regulatory authorities, including the CSRC, jointly adopted the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the M&A Rules, amended in June 2009. The M&A Rules, among other things, require that if an overseas company established or controlled by PRC companies or individuals, or PRC Citizens, intends to acquire equity interests or assets of any other PRC domestic company affiliated with the PRC Citizens, such acquisition must be submitted to the MOFCOM for approval. The M&A Rules also require that an Overseas SPV formed for overseas listing purposes and controlled directly or indirectly by the PRC Citizens shall obtain the approval of the CSRC prior to overseas listing and trading of such Overseas SPV's securities on an overseas stock exchange.

Based on current PRC laws and regulations, our corporate structure and arrangements are not subject to the M&A Rules. However, there are substantial uncertainties as to how the M&A Rules will be interpreted or implemented in the context of an overseas offering, and its opinions summarized above are subject to any new laws, rules and regulations or detailed implementations and interpretations in any form relating to the M&A Rules.

Regulations Relating to Employment

The Labor Law of the People's Republic of China, or the Labor Law, which became effective in January 1995 and was amended in 2018, and the Employment Contract Law of the People's Republic of China, or the Employment Contract Law, effective in January 2008 and amended in 2012, require employers to provide written contracts to their employees, restrict the use of temporary workers and aim to give employees long-term job security. Employers must pay their employees' wages equal to or above local minimum wage standards, establish labor safety and workplace sanitation systems, comply with state labor rules and standards and provide employees with appropriate training on workplace safety. In September 2008, the State Council promulgated the Implementing Regulations for the PRC Employment Contract Law which became effective immediately and interprets and supplements the provisions of the Employment Contract Law.

Under the Labor Contract Law, an employer shall limit the number of dispatched workers so that they do not exceed a certain percentage of its total number of workers. In January 2014, the MOHRSS issued the Interim Provisions on Labor Dispatching, which became effective in March 2014, pursuant to which it provides that the number of dispatched workers used by an employer shall not exceed 10% of the total number of its employees.

The PRC governmental authorities have passed a variety of laws and regulations regarding social insurance and housing funds from time to time, including, among others, the Social Insurance Law of the People's Republic of China, the Regulation of Insurance for Labor Injury, the Regulations of Insurance for Unemployment, the Provisional Insurance Measures for Maternal Employees, the Interim Administrative Provisions on Registration of Social Insurance and the Administrative Regulations on the Housing Provident Fund. Pursuant to these laws and regulations, enterprises in the PRC shall provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, occupational injury insurance and medical insurance, as well as housing fund and other welfare plans. Failure to comply with such laws and regulations may result in various fines and legal sanctions and supplemental contributions to the local social insurance and housing fund regulatory authorities.

Regulations Relating to Environmental Protection

Environmental Protection Law

The Environmental Protection Law of the PRC, or the Environmental Protection Law, was promulgated and effective on December 26, 1989, and most recently amended on April 24, 2014. This Environmental Protection Law has been formulated for the purpose of protecting and improving both the living environment and the ecological environment, preventing and controlling pollution, other public hazards and safeguarding people's health.

According to the provisions of the Environmental Protection Law, in addition to other relevant laws and regulations of the PRC, the Ministry of Environmental Protection and its local counterparts take charge of administering and supervising said environmental protection matters. Pursuant to the Environmental Protection Law, the environmental impact statement on any construction project must assess the pollution that the project is likely to produce and its impact on the environment, and stipulate preventive and curative measures; the statement shall be submitted to the competent administrative department of environmental protection for approval. Installations for the prevention and control of pollution in construction projects must be designed, built and commissioned together with the principal part of the project.

Permission to commence production at or utilize any construction project shall not be granted until its installations for the prevention and control of pollution have been examined and confirmed to meet applicable standards by the appropriate administrative department of environmental protection that examined and approved the environmental impact statement. Installations for the prevention and control of pollution shall not be dismantled or left idle without authorization. Where it is absolutely necessary to dismantle any such installation or leave it idle, prior approval shall be obtained from the competent local administrative department of environmental protection.

The Environmental Protection Law makes it clear that the legal liabilities of any violation of said law include warning, fine, rectification within a time limit, compulsory cease operation, compulsory reinstallation of dismantled installations of the prevention and control of pollution or compulsory reinstallation of those left idle, compulsory shutout or closedown, or even criminal punishment.

As of the date of this report, we are not aware of any warning, investigations, prosecutions, disputes, claims or other proceedings in respect of environmental protection, nor have we been punished or can foresee any punishment to be made by any government authorities of the PRC.

Order on Ecosystem by the Ministry of Ecology and Environment 2019 Classification-based Management on Fixed Pollutant Source

Pursuant to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources, which was promulgated by the Ministry of Ecology and Environment on July 28, 2017 and most recently amended on December 20, 2019. The Ministry of Ecology and Environment implements a classification-based management on the environmental impact assessment, or EIA, of pollutants according to pollutant amount and the impact of the pollutants on the environment as below:

- For those pollutant discharge units with large amount of pollutants and significant environmental impacts, the key management on a pollutant discharge permit is required;
- For those pollutant discharge units with small amount of pollutants and small environmental impacts, the simplified management on a pollutant discharge permit is required; and
- For those pollutant discharge units with very small amount of pollutants and very small environmental impacts, the pollutant discharge registration form is required.

The medical device manufacturing is classified as to fill in a Registration Form. Upon submission of all required documentation, we are registered under the new system by filling in Pollution Source Registration Form.

Regulations Relating to Customer Rights Protection

The PRC Customer Rights and Interests Protection Law, or Customer Protection Law, as amended on October 25, 2013 and effective on March 15, 2014, sets out the obligations of business operators and the rights and interests of the customers. Pursuant to this law, business operators must guarantee that the commodities they sell satisfy the requirements for personal or property safety, provide customers with authentic information about the commodities, and guarantee the quality, function, usage and term of validity of the commodities. Failure to comply with the Customer Protection Law may subject business operators to civil liabilities such as refunding purchase prices, exchange of commodities, repairing, ceasing damages, compensation, and restoring reputation, and even subject the business operators or the responsible individuals to criminal penalties if business operators commit crimes by infringing the legitimate rights and interests of customers.

Regulations Relating to Tax in the PRC

Income Tax

The PRC Enterprise Income Tax Law was promulgated in March 2007 and was most recently amended in December 2018. The PRC Enterprise Income Tax Law applies a uniform 25% enterprise income tax rate to both foreign-invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. Under the PRC Enterprise Income Tax Law, an enterprise established outside China with "de facto management bodies" within China is considered a "resident enterprise" for PRC enterprise income tax purposes and is generally subject to a uniform 25% enterprise income tax rate on its worldwide income. Under the implementation regulations to the PRC Enterprise Income Tax Law, a "de facto management body" is defined as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise.

In April 2009, the Ministry of Finance, or MOF, and SAT jointly issued the Notice on Issues Concerning Process of Enterprise Income Tax in Enterprise Restructuring Business, or the Circular 59. In December 2009, SAT issued the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises, or the Circular 698. Both Circular 59 and Circular 698 became effective retroactively as of January 2008. In March 2011, SAT issued the Notice on Several Issues Regarding the Income Tax of Non-PRC Resident Enterprises, or the SAT Circular 24, effective in April 2011. By promulgating and implementing these circulars, the PRC tax authorities have enhanced their scrutiny over the direct or indirect transfer of equity interests in a PRC resident enterprise by a non-resident enterprise.

In February 2015, SAT issued the Notice on Certain Corporate Income Tax Matters on Indirect Transfer of Properties by Non-PRC Resident Enterprises, or the SAT Circular 7, to supersede existing provisions in relation to the indirect transfer as set forth in Circular 698, while the other provisions of Circular 698 remain in force. SAT Circular 7 introduces a new tax regime that is significantly different from that under Circular 698. SAT Circular 7 extends its tax jurisdiction to capture not only indirect transfers as set forth under Circular 698 but also transactions involving transfer of immovable property in China and assets held under the establishment, and placement in China, of a foreign company through the offshore transfer of a foreign intermediate holding company. SAT Circular 7 also addresses transfer of the equity interest in a foreign intermediate holding company broadly. In addition, SAT Circular 7 provides clearer criteria than Circular 698 on how to assess reasonable commercial purposes and introduces safe harbor scenarios applicable to internal group restructurings. However, it also brings challenges to both the foreign transferor and transferee of the indirect transfer as they have to determine whether the transaction should be subject to PRC tax and to file or withhold the PRC tax accordingly. In October 2017, SAT issued the Announcement on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises, or the SAT Circular 37, amended in June 2018. The SAT Circular 37 superseded the Non-resident Enterprises Measures and SAT Circular 698 as a whole and partially amended some provisions in SAT Circular 24 and SAT Circular 7. SAT Circular 37 purports to clarify certain issues in the implementation of the above regime, by providing, among others, the definition of equity transfer income and tax basis, the foreign exchange rate to be used in the calculation of withholding amount, and the date of occurrence of the withholding obligation. Specifically, SAT Circular 37 provides that where the transfer income subject to withholding at source is derived by a non-PRC resident enterprise in installments, the installments may first be treated as recovery of costs of previous investments. Upon recovery of all costs, the tax amount to be withheld must then be computed and withheld.

Value-Added Tax

The PRC Provisional Regulations on Value-Added Tax were promulgated by the State Council on December 13, 1993, which became effective on January 1, 1994 and were subsequently amended from time to time. The Detailed Rules for the Implementation of the PRC Provisional Regulations on Value-Added Tax (2011 Revision) was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011. On November 19, 2017, the State Council promulgated the Decisions on Abolishing the PRC Provisional Regulations on Business Tax and Amending the PRC Provisional Regulations on Value-Added Tax. Pursuant to these regulations, rules and decisions, all enterprises and individuals engaged in sale of goods, provision of processing, repair, and replacement services, sales of services, intangible assets, real property, and the importation of goods within the PRC territory are VAT taxpayers. On March 21, 2019, the Ministry of Finance, the SAT, and the General Administration of Customs jointly issued the Announcement on Relevant Policies on Deepen the Reform of Value-Added Tax. Sales revenue represents the invoiced value of goods, net of VAT. The VAT is based on gross sales price, starting from April 1, 2019, VAT rate was lowered to 13%.

LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Regulation and Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices promulgated on January 4, 2000, effective on June 1, 2014, amended by the State Council on May 4, 2017 and now effective, and then amended on February 9, 2021 effective on June 1, 2021 ("Regulation on Supervision and Administration of Medical Devices"), the Food and Drug Administration of the State Council shall be responsible for the national administration and supervision of medical devices of the PRC and its local counterparts take charge of the local administration and supervision of medical devices of the PRC.

Under this regulation, medical devices have been classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with low level of risks and whose safety and effectiveness can be ensured through routine administration. Class II medical devices shall refer to those devices with moderate risks that must be strictly controlled and regulated to ensure their safety and effectiveness. Class III medical devices shall refer to those devices with relatively high risks that must be strictly controlled and regulated through special measures to ensure their safety and effectiveness.

The products we currently manufacture and sell include Class I, II and III disposable medical devices.

Registration and Filings of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices and the Administrative Measures for the Registration of Medical Devices promulgated by CFDA on July 30, 2014 and came into effect on October 1, 2014 ("the Supervision and Administration of Medical Devices" was amended and came into effect on May 4, 2017; and which was then amended on February 9, 2021 and came into effect on June 1, 2021), Class I medical devices are subject to filing administration, and Class II and Class III medical devices are subject to pre-approval registration administration. A registration certificate for Class II and Class III medical devices are issued upon approval, which is valid for five years and may be renewed six months prior to its expiration date.

Clinical trials are not required for the filing of the Class I medical devices, but necessary for the registration of Class II and Class III medical device with certain exceptions.

As of the date of this report, we are current on the registration and filing of medical devices.

Production License for Medical Devices

Pursuant to the Regulation on the Supervision and Administration of Medical Devices promulgated on July 30, 2014 and came into effect on October 1, 2014, as amended in 2017 and came into effect on May 4, 2017 (amended on February 9, 2021, came into effect on June 1, 2021), and the Administrative Measures on the Production Supervision of Medical Devices promulgated on July 30, 2014 and came into effect on October 1, 2014, as amended in 2017 and came into effect on November 11, 2017, manufacturers engaged in the manufacturing of Class I medical devices are subject to production filing administration and receive production filing certificates upon satisfaction of filing requirements; while those engaged in the manufacturing of Class II and Class III medical devices are subject to pre-approval licensing administration and receive medical device production licenses upon receipt of approval for licensing. A medical device production license is valid for five years and may be renewed six months prior to its expiration date.

In addition, a manufacturer of medical devices shall satisfy the following conditions:

(1) possessing production sites, environmental conditions, production equipment and professional technicians that are suitable for such medical device produced;

(2) possessing organizations or professional examination staff and examination equipment that carry out quality examination for such medical device produced;

(3) formulating a management system which ensures the quality of such medical device;

(4) having capability of after-sale services that is suitable for such medical device produced; (5) satisfying the requirements as prescribed in production R&D and production technique documents.

As of the date of this report, we are current on the production filing and licensing of the medical devices.

Production and Quality Management of Medical Devices

Pursuant to the Administrative Measures on the Supervision of the Production of Medical Devices promulgated on December 29, 2014 and came into effect on March 1, 2015, as amended in 2017 and came into effect on November 17, 2017, and the Standards on Production and Quality Management of Medical Devices promulgated by the CFDA on December 29, 2014 and came into effect on March 1, 2015, an enterprise engaged in the production of medical devices shall establish and effectively maintain a quality control system in accordance to the requirements of the Standards on Production and Quality Management of Medical Devices. The enterprise engaged in the production of medical devices shall regularly conduct comprehensive self-inspection on the operation of quality management system and submit this report to the local food and drug supervision and administration authorities before the end of every year. The enterprise shall also establish its procurement control procedure and assess its suppliers by establishing an examination system to ensure the purchased products are in compliance with the statutory requirements. The enterprise shall apply risk management to the whole process of design and development, production, sales and after-sale services.

Pursuant to The Notice of Four Guidelines including On-site Inspection Guidelines for the standards on Production and Quality Management of Medical Devices promulgated by the CFDA on September 25, 2015 and came into effect on September 25, 2015, during the course of on-site verification of the registration of medical devices and on-site inspection of production license t(including change production license), the inspection team shall, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which shall be divided into "Passed," "Failed" and "Reassessment after rectification." During the supervision and inspection, if it is found that the requirements of the key items or ordinary items that may have direct impact on product quality are not satisfied, the enterprise shall suspend production and go through rectification. If it is found that the requirements of the ordinary items are not satisfied, and it does not directly affect product quality, the enterprise shall rectify in a prescribed time. The regulatory authorities will examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group and issue the final inspection results.

The inspection team has conducted several on-site inspections on our standards of production and quality management of medical devices during the track record period, the recommended conclusions issued by the inspection team were "Passed" or "Rectification within the prescribed period." The matters with respect to "Rectification within the prescribed period" have been rectified within the prescribed period and submitted to the inspection team.

According to the on-site inspections on our standards of production and quality management conducted by competent authorities, we are in compliance with the requirements of the standards on production and quality management of medical devices.

Good Clinical Practice for Medical Devices

On March 1, 2016, the CFDA and the National Health and Family Planning Commission jointly promulgated the Good Clinical Practice for Medical Devices, which became effective as of June 1, 2016. The regulation includes full procedures of clinical trial of medical devices, including, among others, the protocol design, conduction, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial.

For conducting clinical trials of medical devices, an applicant shall organize to formulate scientific and reasonable clinical trial protocol based on the categories, risks and intended use of the medical devices for the clinical study. The applicant shall be responsible for organizing to develop and revise of the researcher's manual, clinical trial protocol, informed consent form, case report form, relevant standard operating procedures and other relevant documents, and shall be responsible for organizing necessary trainings for the clinical trials. The applicant shall select the clinical trial institutions and its researchers from the qualified medical device clinical trial institutions according to the characteristics of the medical devices to be used in the clinical study.

As an applicant for clinical trials of medical devices, we are responsible for initiating, applying, organizing and monitoring such clinical trials, and shall be responsible for the authenticity and reliability of the clinical trials.

Operation License for Medical Device

Pursuant to the Regulations on the Supervision and Administration of Medical Devices and the Administrative Measures on the Operation Supervision of Medical Devices, promulgated on July 30, 2014 and came into effect on October 1, 2014 and last amended on March 10, 2022, filing and licensing are not required for the operation of Class I medical devices. Operators engaged in the operation of Class II medical devices are subject to filing administration and will receive medical device operation filing certificate upon satisfaction of filing requirement, while operators engaged in the operation of Class III medical devices are subject to pre-approval licensing administration and will receive medical device operation license upon receipt of approval for licensing. A medical device operation license is valid for five years and may be renewed six months prior to its expiration date.

To engage in business operations of medical devices, the following requirements shall be met:

1. Having a quality control institution or staff corresponding to the business scope and scale, and the staff shall have relevant education or professional titles certified by the state.

2. Having an operation and storage premise corresponding to the business scope and scale.

3. Having storage conditions corresponding to the business scope and scale; warehouses are not required if all storage is commissioned to other operators of medical devices.

4. Having a quality control system corresponding to the medical devices concerned.

5. Possessing the capability of professional guidance, technical training and after-sale service corresponding to the medical devices it operates; or it has come into an agreement on technical support with a relevant institution.

An enterprise to be engaged in business operations of Category III medical devices shall also have a computerized information management system compliant with quality standards to ensure traceability of products. An enterprise to be engaged in business operations of Category I or Category II medical devices is encouraged to set up such a system.

As of the date of this report, we are current on the operation filing and licensing of the medical devices.

Special Procedures for Examination and Approval of Innovative Medical Devices

On October 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices, which aims to encourage the innovation for medical devices.

Pursuant to the Opinions, the priority review and approval will be applicable to innovative medical devices supported by the National Science and Technology Major Projects and the National Key R&D Program of China, and the clinical trials of which having been conducted by the National Clinical Research Center, and approved by the management department of National Clinical Research Center. Pursuant to the Special Procedures for Examination and Approval of Innovative Medical Devices which were promulgated by the NMPA on November 2, 2018 and came into effect on December 1, 2018, special procedures shall be applicable to the examination and approval for medical devices in the following circumstances:

(1) if the applicant legally owns the invention patent of the core technology of the product through its technological innovation activities in the PRC, or legally obtained the invention patent or the right of use thereof through transfer in the PRC, and that the interval between the date of application for the special examination and approval of innovative medical devices to the date of authorized publication should not exceed five years; or the patent administration department of the State Council has disclosed the application for the invention patent of the core technology and the Patent Search and Consultation Center of the National Intellectual Property Administration of the PRC has issued the patent search report setting out the novelty and innovation of the core technology solution of the product;

(2) the applicant has developed the prototype product and completed the preliminary research under a true and controllable process that generated complete and traceable data;

(3) the product has major working mechanism or mechanism of action which is the first of its kind in the PRC, has fundamental improvement in product performance or safety compared with similar products, is of an internationally leading standard in terms of techniques and has significant clinical value. The Center for Medical Device Evaluation of the NMPA should give priority to the innovative medical devices in their technical review upon receiving the registration application, after which the NMPA will give priority to the product in their administrative approval.

Advertisements of Medical Devices

Pursuant to the Regulations on Tentative Measures for the Censorship of Advertisement for Drugs, Medical Devices, Dietary Supplements, Food Formula for Special Medical Purpose promulgated by SAMR on December 24, 2019 and came into effect on March 1, 2020, the State Administration for Market Regulation is responsible for organizing and guiding the review of advertisements for drugs, medical devices, health foods and formula foods for special medical purposes. The administrations for market regulation and drug administrations (hereinafter referred to as the “advertisement review authorities”) of all provinces, autonomous regions and centrally administered municipalities shall be responsible for the review of advertisements for drugs, medical devices, health food and formula food for special medical purposes, and may entrust other administrative authorities to implement review of advertisements pursuant to the law.

The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate and shall not contain any false or misleading contents. Advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for drugs, medical devices, health food and formula food for special medical purposes.

National Medical Insurance Program

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. Pursuant to the Opinions on the Establishment of the New Rural Cooperative Medical System forwarded by the General Office of the State Council on January 16, 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has since spread to the whole nation. The State Council promulgated the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In 2015, the PRC government announced the Outline for the Planning of the National Medical and Health Service System (2015-2020) which aims to establish a basic medical and health care system that covers both rural and urban citizens by 2020. On January 3, 2016, the State Council issued the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents to integrate the Urban Resident Basic Medical Insurance and the New Rural Cooperative Medical System and the establishment of a unified Basic Medical Insurance for Urban and Rural Residents, which will cover all urban and rural non-working residents expect for rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees.

With regard to reimbursement for medical devices and diagnostic tests, the Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the National Urban Employees Basic Medical Insurance Scheme (Lao She Bu Fa [1999] No. 22) prescribes the coverage of diagnostic and treatment devices and diagnostic tests where part of the fees is paid through the basic medical insurance scheme. It also includes a negative list that precludes certain devices and medical services from governmental reimbursement. Detailed reimbursement coverage and rate for medical devices and medical services (including diagnostic tests and kits) are subject to each province's local policies.

Export Registration

Pursuant to the Regulation on the Supervision and Administration of Medical Devices and the Measures for the Supervision and Administration of Medical Device Production promulgated by the CFDA and amended on November 11, 2017 and March 10, 2022, CFDA, in accordance with the spirit of the Notice of Guo Ban Fa [94] No. 66 of the State Council, conducts inspections of safety and legality of the exported products manufactured by domestic enterprises, grants legitimate production license in China (if these products are sold within Chinese territory). In accordance with international practice, the quality of exported medical devices is mainly supervised by the importing countries. However, some importing countries/regions may require exporting enterprises to provide Medical Device Product Export Sales Certificates issued by the CFDA. Pursuant to Announcement on Issuing the Provisions on the Administration of Medical Device Product Export Sales Certificates, promulgated by the CFDA and effective on September 1, 2015, such exporting enterprises may apply to the provincial departments of the CFDA at the places where enterprises are located for Medical Device Product Export Sales Certificates.

The premise of obtaining Medical Device Product Export Sales Certificates is that the relevant production enterprises have obtained medical device product registration certificates and production licenses or have undergone the formalities for recordation and production recordation of medical device products in China. The valid period of Medical Device Product Export Sales Certificates, except being specified for one time use, shall not expire after the earliest deadline of any certificate among various certificates submitted by the enterprise amid the application materials, and shall be no longer than two years. Where the relevant materials submitted by an enterprise change, the enterprise shall report to the certificate issuing department in a timely manner. Where the relevant materials change, or the Medical Device Product Export Sales Certificate still needs to be used after its expiration, the enterprise shall apply for a new Medical Device Product Export Sales Certificate. Where the CFDA find that any relevant enterprises fail to meet the requirements of relevant regulations on production, they shall downgrade the credit ratings of such enterprises to lower levels; or, when any enterprises are considered failing to meet the requirements for issuance of certificates anymore, or the relevant materials submitted by the enterprises change, the provincial CFDA departments shall notify the relevant information in a timely manner.

Two-invoice System

According to the Notice of Publishing Opinions on Implementing Two-invoice System in Drug Procurement Among Public Medical Institutions (For Trial Implementation) which was issued on December 26, 2016, the "two-invoice system" refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The wholly owned or holding commercial company (only one commercial company is permitted in the whole country) or the domestic general agent for overseas drugs (only one domestic agent is permitted in the whole country) established by a pharmaceutical manufacturer or a group enterprise integrating science, industry and trade may be regarded as a manufacturer. The allocation of drugs between a pharmaceutical distribution group enterprise and its wholly owned (holding) subsidiaries or among its wholly owned (holding) subsidiaries may not be regarded as a process for which an invoice should be issued, but one invoice is allowed to be issued at most.

Currently, some provinces in the PRC have formulated relevant rules and regulations to implement the "two-invoice system" in the field of medical consumables, for instance, the Notice on the Sharing of Transparent Procurement Results of Medical Devices (Medical Consumables) across the Province promulgated by the Fujian Provincial Medical Security Management Committee Office in July 2018, the Notice on Further Promoting the "Two Invoice System" on Medicines and Medical Consumables issued by eight local government departments of Shaanxi Province including Deepen Medical and Healthcare System Reform Leading Group Office of Shaanxi Province in July 2018, and the Opinions on Implementation of the "Two Invoice System" in Medical Consumables Procurement by Public Medical Institutions in Anhui Province (for Trial Implementation) issued by five local government departments of Anhui Province including Food and Drug Administration of Anhui Province in November 2017.

LAWS AND REGULATIONS RELATING TO LAND USE

Overview of relevant PRC Laws and Regulations on Land Use Rights

Pursuant to relevant PRC land laws and stipulations, there are two kinds of land in China: 1) collectively owned land, which is normally owned by the farmers or village for agricultural use; and 2) state owned land which is sub-divided into allocated and granted land use rights. Allocated land are land rights granted by the Chinese government to an entity for a particular purpose (e.g., research, military, medical etc.). These allocated rights are inferior in that they must be used for the specified purpose and cannot be transferred, leased or mortgaged. Granted land, on the other hand, is paid for and can be used for commercial and industrial purposes. These land use rights are the preferred land use rights for foreign investors as they are freely transferable (subject normally to the land being developed, as undeveloped land cannot normally be sold), leased and mortgaged. Land may be designated for commercial, industrial, residential or other purposes and may not be used for any non-designated purpose. The land authorities may impose administrative sanctions, including fines, injunction orders or even confiscation of the land use rights, for any breach of this provision. The term of land use rights varies depending on the designated purpose. A land user may extend the term by entering into a contract to extend the term and pay an additional land grant fee to the land authorities. Upon the execution of a land use rights grant contract and payment of the land grant fee, owners of land use rights will be issued a State-owned land use certificate, which sets forth, among other things: (i) the nature (granted or allocated); (ii) designated purpose; (iii) term of the land use rights; (iv) the location and area of the land; and (v) whether the land use rights are subject to any security interest. This certificate is the primary evidence of legal and valid land use rights.

Overview of relevant PRC Laws and Regulations on Buildings

It is required under the PRC law to obtain relevant permits from different authorities before commencing the construction of a building. The required permits are, inter alia, a State-owned Land Use Certificate, a Planning Permit of Land for Construction Use, a Planning Permit of Construction Project, and a Commencement Permit of Construction Project (except for those projects where the construction investment is less than RMB 300,000 or the construction area is less than 300 square meters). After the completion of construction, the owner shall also apply at relevant authorities for inspection and acceptance of the construction project and then obtain a Certificate for Completion Acceptance of Construction Project as well as a Title Certificate for Building. Further, pursuant to relevant PRC laws and regulations, the premises title certificate is the only legal certificate by which the owner legally has the ownership in respect of the building and thereby exercises rights to possess, utilize, profit from and dispose of the premises. Without such certificate, it is not permitted to transfer the premises.

According to the Urban and Rural Planning Law of the PRC, if a rural construction planning permit is not obtained in accordance with the law or construction is not carried out in accordance with the provisions of the rural construction planning permit, the township or town people's government shall order the construction to stop and make corrections within a time limit.

Not all the buildings of Jiangsu Yada and Jiangsu Huadong attached on the land have appropriate title certificates. The buildings not granted title certificate are at a risk of being dismantled or other administrative penalties if they are identified as illegal buildings due to the violation of the PRC Land Administration Law, the PRC Law on Urban and Rural Planning, and other relevant laws and regulations.

Regulation and Classification of Land Allocation

According to the PRC Land Administration Law, the State legally adopts the system of compensation for the use of land owned by the State, except where the State allocates the right to use state-owned land within the bounds of the law; A construction project developer utilizing state-owned land shall generally obtain the use right of state owned land through paid means such as granting for compensation. The following categories of land may be directly allocated with the lawful approval of the people's governments at or above the county level: (1) land for use by government institutions or the military; (2) land for urban infrastructure or public welfare projects; (3) land for energy, transportation. and water conservancy projects as well as other infrastructure projects supported by the government; and (4) other land as provided for by laws or administrative regulations. In addition, according to the Provisions on the Economical and Intensive Use of Land (promulgated by Order No.61 of the Ministry of Natural Resources on May 22, 2014 and amended in accordance with the Decision of the Ministry of Natural Resources on the First Group of Repealed and Amended Departmental Rules adopted at the 2nd executive meeting of the Ministry of Natural Resources on July 16, 2019), except that land for military use, affordable housing, or other special purposes such as national security or public order may be supplied without consideration by means of allocation, payment is required for land used for business purposes, including land used for office space of state authorities, transportation, energy, or water conservancy and other infrastructure (industry), urban infrastructure and various social undertakings; the land user and land prices for commercial use shall be determined by means of bidding, auction, or listing. The acquisition and use of allocated land by enterprises shall comply with the special restrictions as prescribed by laws and regulations.

Pursuant to Interim Regulations of the People's Republic of China Concerning the Assignment and Transfer of the Right to the Use of the State-owned Land in the Urban Areas, promulgated by the State Council and amended on November 29, 2020, the allocated right to the use of the land may not be transferred, leased, or mortgaged, with the exception of cases as specified in following cases and subject to the approval of the land administration departments and the housing administration departments under the people's governments at the municipal and county levels: (i) the land users are companies, enterprises, or other economic organizations, or individuals; (ii) a certificate for the use of state-owned land had been obtained; (iii) possessing legitimate certificates of property rights to the above-ground buildings and other attached objects; and (iv) a contract for assigning the right to the use of land is signed in accordance with the regulations and the land user makes up for the payment of the assignment fee to the local municipal or county people's government or uses the proceeds resulting from the transfer, lease or mortgage to pay the assignment fee. Any units or individuals that transfer, lease or mortgage the allocated right to the use of the land without authorization shall have their illegal incomes thus secured confiscated by the land administration departments under the people's governments at the municipal and county levels and shall be fined in accordance with the seriousness of the case.

C. Organizational Structure

See "—A. History and Development of the Company."

D. Property, Plants and Equipment

Property, Plants, and Equipment

Our PRC headquarters, manufacturing facilities and office spaces are located in Yangzhou, Jiangsu Province, PRC.

Land Use Rights We Obtained

We obtained the following land use rights for the construction of our headquarters, manufacturing facilities and office spaces, which cover an aggregate lot area of approximately 383,172 square feet (equivalent to 35,597.84 square meters), with the breakdown of land use set forth in the table below:

Land User	Land Use Type	Description/Use	Location	Lot Area (Square Meters)
Yangzhou Huada	Allocation	Industrial land	Tongda Road, Touqiao Town, Hanjiang District, Yangzhou	6,700.24
Jiangsu Yada	Assignment	Industrial land	Xinqiao Village, Touqiao Town, Guangling District, Yangzhou	15,991.00
Jiangsu Huadong	Allocation	Industrial land	No.88 Tongda Road, Touqiao Town, Guangling District, Yangzhou	11,717.44
Jiangsu Yada	Allocation	Industrial land	Tongda Road, Touqiao Town, Hanjiang District, Yangzhou	1,189.16
Total				35,597.84

Properties We Own

We own the premises of our headquarters, manufacturing facilities and office spaces, which cover an aggregate building area of approximately 246,538 square feet (equivalent to 22,904.12 square meters), with the breakdown of square footage set forth in the table below:

Description/Use	Owner	Location	Area (Square Meters)
Manufacturing facility	Jiangsu Yada	No.58 Yada Road, Touqiao Town	Land Lot Area 15,991.00/ Building Area 3,545.09 (Floors 1-4)
Manufacturing facility	Jiangsu Yada	No.58 Yada Road, Touqiao Town	Land Lot Area 15,991.00/ Building Area 394.62 (Floor 1)
Manufacturing facility	Jiangsu Yada	No.58 Yada Road, Touqiao Town	Land Lot Area 15,991.00/ Building Area 2,412.30
Manufacturing facility	Jiangsu Yada	No.58 Yada Road, Touqiao Town	Land Lot Area 15,991.00/ Building Area 428.79 (Floor 1)
Manufacturing facility	Yangzhou Huada	No.1 East Tongda Road, Touqiao Town	Land Lot Area 6,700.24/ Building Area 2,109.77 (Floors 1-2)
Office space & manufacturing facility	Yangzhou Huada	No.2,3,4 East Tongda Road, Touqiao Town	Land Lot Area 6,700.24 464.2 (Floor 1)；1,224.45 (Floors 1-2)；1,005.73 (Floor 1)
Manufacturing facility	Jiangsu Yada	No.1 Zhu Group, Xuzhuang, Datong Village, Touqiao Town	3,023.2
Manufacturing facility	Jiangsu Huadong	No.88 Tongda Road, Touqiao Town	Land Lot Area 11717.44/ Building Area 3,709.93 (Floors 1-2)
Manufacturing facility	Jiangsu Huadong	No.88 Tongda Road, Touqiao Town	Land Lot Area 11717.44/ Building Area 4,586.04 (Floors 1-2)
Total			22,904.12

Properties We Lease

In addition to the above-mentioned properties that we own, we currently lease several properties in Yangzhou for an aggregate area of approximately 85,241 square feet (equivalent to 7,919 square meters) from our PRC subsidiaries for processing shops and office space. All leases are subject to renewal upon approval of the lessors, subject to the lessor receiving renewal requests at least three months in advance. Presently, the leases have been renewed through 2023.

The breakdown of the leased properties is as follows:

Lessor/Rental Cost per month	Lessee	Location	Area (Square Meter)	Annual Rent	Term	Use
Jiangsu Huadong	Yangzhou Huada	No.88 Tongda Road, Guangling District, Yangzhou	670	$5,828 (RMB40,200.00)	January 1, 2023 to December 31, 2023	Processing Workshop
Jiangsu Yada	Yangzhou Huada	No.88 Tongda Road, Guangling District, Yangzhou	20	$174 (RMB1,200.00)	January 1, 2023 to December 31, 2023	Office
Jiangsu Huadong	Jiangsu Yada	No.88 Tongda Road, Guangling District, Yangzhou	1,100	$9,569 (RMB66,000.00)	December January 1, 2023 to December 31, 2023	Processing Workshop
Yangzhou Huada	Jiangsu Huadong	No.88 Tongda Road, Guangling District, Yangzhou	4,804.15	$41,792 (RMB288,249.00)	January 1, 2023 to December 31, 2023	Processing Workshop
Jiangsu Yada	Jiangsu Huadong	No.88 Tongda Road, Guangling District, Yangzhou	1,325.00	$11,526 (RMB79,500.00)	January 1, 2023 to December 31, 2023	Office

* Zhu Yi is not a related party to the Company.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion of our financial condition and results of operations is based upon and should be read in conjunction with our consolidated financial statements and their related notes included in this Annual Report. This report contains forward-looking statements. In evaluating our business, you should carefully consider the information provided under the caption "Item 3. Key Information—D. Risk Factors" in this Annual Report. We caution you that our businesses and financial performance are subject to substantial risks and uncertainties.

A. Operating Results

Business Overview

Meihua International Medical Technologies Co., Ltd., through its operating subsidiaries, is mainly engaged in the manufacture, research and development and sales of Class I, II and III medical devices. It has a history of more than 30 years and has a multiple product categories, with more than 800 domestic products and more than 120 export products. The main product lines include disposable infusion pumps, anesthesia puncture kits, electronic pumps, full anesthesia kits, urethral catheterization kits, gynecological examination kits, endotracheal intubation, dressing applications and various tubes. It is the leading enterprise in China's medical consumables industry. The Company has received qualification to manufacture and produce China's first, second and third type of medical device consumables and, at the same time, the Company has acquired FDA registration and the European Union's CE certification. Relevant permissions have been obtained in major sales markets to meet local regulatory requirements.

The Company's distribution network covers major global markets. Internationally, the Company mainly exports medical devices through exporting distributors. To date, the Company has 324 exporting distributors responsible for distributing its products to end users in Europe, North America, Asia, South America, Africa, and Oceania. In the Chinese market, the Company sells products under its own brand to customers all over the country. The Company's product permeation for mainland China has reached major medical institutions and pharmacies through some 3,004 distributors. At the same time, the Company has established a cooperative network with more than 525 hospitals through its own direct sales channels.

Revenues decreased by $691,369, or approximately 1%, to $103,346,341 for the year ended December 31, 2022 from $104,037,710 for the year ended December 31, 2021. The decrease was mainly due to a decline in demand for customer orders.

Net income decreased by $14,771,875, or approximately 71%, to $6,177,704 for the year ended December 31, 2022 from $20,949,579 for the year ended December 31, 2021. The decrease was mainly due to a sharp increase in service expenses and the write-off of the Tai He deposit.

Revenues increased by $14,976,700, or approximately 17%, to $104,037,710 for the year ended December 31, 2021 from $89,061,010 for the year ended December 31, 2020. The increase was mainly due to the Company's business expansion, research and development of new products and development of new customers.

Net income increased by $1,904,324, or approximately 10%, to $20,949,579 for the year ended December 31, 2021 from $19,045,255 for the year ended December 31, 2020.

Coronavirus (COVID-19) Update

On January 30, 2020, the World Health Organization declared the outbreak of the corona-virus disease (COVID-19) a "Public Health Emergency of International Concern," and on March 11, 2020, the World Health Organization characterized the outbreak as a "pandemic." Governments in affected countries have imposed travel bans, quarantines and other emergency public health measures, which have caused material disruption to businesses globally and result in an economic slowdown. These measures, though temporary in nature, may continue and increase depending on developments in the COVID-19's outbreak.

In fiscal year 2020, COVID-19 had a significant impact on our business and results of operations as the sales volume of masks rose sharply, while at the same time sales of products other than masks declined due to a decrease in market demand. In fiscal year 2021, as circumstances surrounding the COVID-19 epidemic stabilized within the PRC, the market for masks was no longer in urgent shortage compared to the same period in 2020, and the production of other epidemic prevention products resumed normal production levels. In general, with the precise control of the epidemic in the PRC, our production and operations recovered smoothly, and the demand for other products has increased gradually.

After the initial outbreak of COVID-19, from time to time, some instances of COVID-19 infections have emerged in various regions of China, including the infections caused by the Omicron variants in 2022. For example, a wave of infections caused by the Omicron variants emerged in Shanghai in 2022, and a series of restrictions and quarantines were implemented to contain the spread.

Many of the restrictive measures previously adopted by the PRC governments at various levels to control the spread of the COVID-19 virus have been revoked or replaced with more flexible measures since December 2022. While the revocation or replacement of the restrictive measures to contain the COVID-19 pandemic could have a positive impact on our normal operations, the extent of the impact on the Company's future financial results will be dependent on future developments such as the length and severity of the crisis, the potential resurgence of the crisis, future government actions in response to the crisis and the overall impact of the COVID-19 pandemic on the global economy and capital markets, among many other factors, all of which remain highly uncertain and unpredictable. Given this uncertainty, the Company is currently unable to quantify the expected impact of the COVID-19 pandemic on its future operations, financial condition, liquidity and results of operations if the current situation continues.

In preparing these consolidated financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through December 31, 2022, the date the consolidated financial statements were available to be issued. No events require additional adjustment to or disclosure in the consolidated financial statements.

Results of Operations

The following table sets forth a summary of our consolidated results of operations for the periods presented. This information should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report. The results of operations in any period are not necessarily indicative of our future trends.

(Amounts expressed in U.S. dollars, except share data and per share data, or otherwise noted)

Years Ended December 31, 2022, 2021 and 2020

	For the Year Ended December 31,		
	2022	**2021**	**2020**
Revenues			
Third party sales	$ 103,317,145	$ 103,461,809	$ 88,244,403
Related party sales	29,196	575,901	816,607
Total revenues	103,346,341	104,037,710	89,061,010
Cost of revenues	65,247,864	64,232,469	51,900,823
Gross profit	38,098,477	39,805,241	37,160,187
Operating expenses			
Selling	7,109,524	6,457,801	6,624,332
General and administrative	12,468,551	4,361,472	4,577,570
Research and development	2,962,904	2,725,014	2,492,059
Written-off Tai He deposit	4,755,536	-	-
Total operating costs and expenses	27,296,515	13,544,287	13,693,961
Income from operations	10,801,962	26,260,954	23,466,226
Other (income) expense:			
Interest expense	194,667	180,744	137,160
Interest income	(63,725)	(23,855	(36,583)
Currency exchange gain	(273,432)	(174,413)	(393,478)
Other expense, net	53,205	50,437	25,551
Total other (income) expenses	(89,285)	32,913	(267,350)
Income before income tax provision	10,891,247	26,228,041	23,733,576
Income taxes expense	4,713,543	5,278,462	4,688,321
Net income	$ 6,177,704	$ 20,949,579	$ 19,045,255

Year ended December 31, 2022 compared to year ended December 31, 2021

Revenues

Revenues decreased by $691,369, or approximately 1%, to $103,346,341 for the year ended December 31, 2022 from $104,037,710 for the year ended December 31, 2021. The decrease was mainly due to a decline in demand for customer orders.

Cost of revenues

Cost of revenues primarily include cost of materials, direct labor costs, overhead, and other related incidental expenses that are directly attributable to the Company's principal operations. Cost of revenues increased by $1,015,395, or approximately 2%, to $65,247,864 for the year ended December 31, 2022 from $64,232,469 for the year ended December 31, 2021. The increase was mainly due to an increase in the price of materials.

Gross profit margin

The following table sets forth the overall gross profit margin of the Company:

	For the Year Ended December, 31	
	2022	**2021**
Revenues	$ 103,346,341	$ 104,037,710
Costs of revenues	65,247,864	64,232,469
Gross profit	$ 38,098,477	$ 39,805,241
Gross profit margin %	37%	38%

Gross profit decreased by $1,706,764, or approximately 4%, to $38,098,477 for the year ended December 31, 2022 from $39,805,241 for the year ended December 31, 2021. Gross profit margin decreased from 38% for the year ended December 31, 2021 to 37% for the year ended December 31, 2022 due to an increase in the cost of materials.

Operating costs and expenses

Our operating costs and expenses consist of selling expenses, general and administrative expenses and research and development expenses.

Selling

The following table sets forth a breakdown of the selling expenses of the Company:

Years Ended December 31, 2022 and 2021

	2022	**2021**
Transportation expenses	$ 2,585,485	$ 2,802,680
Salaries and benefits	1,468,247	1,287,436
Entertainment expenses	1,178,064	786,226
Conference expenses	1,125,353	774,298
Travel allowance	343,439	341,165
Auto expenses	243,706	168,832
Advertising expenses	95,432	21,498
Other expenses	69,798	275,666
Total	$ 7,109,524	$ 6,457,801

Selling expenses increased by $651,723, or approximately 10%, to $7,109,524 for the year ended December 31, 2022 from $6,457,801 for the year ended December 31, 2021. The increase was mainly attributable to the combined effects of the followings:

(a) Our conference expenses increased by $351,055 to $1,125,353 for the year ended December 31, 2022 from $774,298 for the year ended December 31, 2021. Conference expenses are mainly related to the company's market expansion, business development, business negotiation, medical expo, and exhibition affairs. These expenditures helped the Company promote its products, develop markets and channels, strengthen customer communication, and establish long-term and stable cooperative relations;

(b) Our transportation expenses decreased by $217,195, or approximately 8%, to $2,585,485 for the year ended December 31, 2022 from $2,802,680 for the year ended December 31, 2021. The reduction in business travel was impacted by COVID-19 related controls implemented by local governments in fiscal year 2022;

(c) Our salaries and benefits expenses increased by $180,811 or approximately 14%, to $1,468,247 for the year ended December 31, 2022 from $1,287,436 for the year ended December 31, 2021. The increase was mainly attributable to the fact that the COVID-19 pandemic in China had been largely brought under control and the local government cancelling the related social insurance relief policy.

(d) Our entertainment expenses increased by $391,838, or approximately 50%, to $1,178,064 for the year ended December 31, 2022 from $786,226 for the year ended December 31, 2021. The increase was mainly attributable to the Company's business expansion and new customer acquisition.

General and administrative

General and administrative expenses primarily consist of the following expenses:

Years Ended December 31, 2022 and 2021

	2022	2021
Salaries and benefits	$ 1,362,803	$ 1,227,228
Entertainment expenses	1,230,556	816,196
Conference fee	846,374	510,267
Auto expenses	226,763	153,911
Maintenance expenses	129,425	126,650
Depreciation expenses	104,295	147,522
Travel allowance	131,872	118,113
Office expenses	102,417	94,686
Surtax expenses	642,748	655,679
Amortization expenses	22,196	26,951
Rental expenses	7,515	20,349
Insurance expenses	108,146	9,743
Service expenses	7,200,839	183,647
Other expenses	352,602	270,530
Total	$ 12,468,551	$ 4,361,472

General and administrative expenses increased by $8,107,079, or approximately 186%, to $12,468,551 for the year ended December 31, 2022, from $4,361,472 for the year ended December 31, 2021. The increase was primarily due to (a) service expenses increasing by approximately $7.0 million from approximately $0.2 million for the year ended December 31, 2021 to approximately $7.2 million for the year ended December 31, 2022, (b) entertainment expenses increasing by $414,360 or 51% from approximately $0.8 million for the year ended December 31, 2021 to approximately $1.2 million for the year ended December 31, 2022, (c) conference fee expenses increasing by approximately $0.3 million from approximately $0.5 million for the year ended December 31, 2021 to approximately $0.8 million for the year ended December 31, 2022, and (d) salaries and benefits increasing by approximately $0.1 million from approximately $1.2 million for the year ended December 31, 2021 to approximately $1.4 million for the year ended December 31, 2022.

Research and development

The following table sets forth a breakdown of the research and development expenses of the Company:

Years Ended December 31, 2022 and 2021

	2022	2021
Sample manufacturing expenses	$ 1,392,350	$ 1,205,437
Salaries and benefits	1,161,696	1,093,717
Travel allowance	123,373	116,266
Depreciation expenses	8,309	8,161
Design expenses	98,068	110,265
Material expenses	27,371	46,103
Other expenses	151,737	145,065
Total	$ 2,962,904	$ 2,725,014

The research and development expenses increased by $237,890, or approximately 9%, to $2,962,904 for the year ended December 31, 2022, from $2,725,014 for the year ended December 31, 2021. The increase was mainly due to the increase in salaries and benefits expenses which was mainly attributable to that the pandemic in China had been brought under control and the local government had canceled the social insurance relief policy.

Income from operations

As a result of the factors described above, our income from operations decreased by $15,458,992, or approximately 59%, to $10,801,962 for the year ended December 31, 2022 from $26,260,954 for the year ended December 31, 2021.

Income tax expense

The provision for income taxes decreased by $564,919, or approximately 11%, to $4,713,543 for the year ended December 31, 2022, from $5,278,462 for the year ended December 31, 2021. The decrease was mainly due to the decrease of profit before provision for income taxes in 2021.

Net income

As a result of the factors described above, our net income decreased by $14,771,875, or approximately 71%, to $6,177,704 for the fiscal year ended December 31, 2022 from $20,949,579 for the fiscal year ended December 31, 2021.

Unrealized foreign currency translation adjustment

The Company's reporting currency is the United States dollar ("US$"). The Company's operations are primarily conducted through the PRC subsidiaries where the local currency is the functional currency. The functional currency of Kang Fu HK is the Hong Kong dollar and the functional currency of Huada, Yada, Huadong and Guanghui is the Renminbi ("RMB"). Results of operations and cash flows are translated at average exchange rates during the period, assets and liabilities are translated at the unified exchange rate at the end of the period and equity is translated at historical exchange rates. Translation adjustments resulting from the process of translating the financial statements denominated in RMB into U.S. dollars are included in other comprehensive income. Our foreign currency translation loss for the fiscal year ended December 31, 2022 was $9,155,028, compared to the foreign currency translation gain of $2,083,243 for the fiscal year ended December 31, 2021. The change was primarily due to the exchange rate fluctuation of RMB against the U.S. dollars.

Year ended December 31, 2021 compared to year ended December 31, 2020

Revenues

Revenues increased by $14,976,700, or approximately 17%, to $104,037,710 for the year ended December 31, 2021 from $89,061,010 for the year ended December 31, 2020. The increase was mainly due to the Company's business expansion, research and development of new products and development of new customers.

Cost of revenues

Cost of revenues primarily include cost of materials, direct labors, overhead, and other related incidental expenses that are directly attributable to the Company's principal operations. Cost of revenue increased by $12,331,646, or approximately 24%, to $64,232,469 for the year ended December 31, 2021 from $51,900,823 for the year ended December 31, 2020. The increase was mainly attributable to an overall increase in sales during fiscal year 2021.

Gross profit margin

The following table sets forth the overall gross profit margin of the Company:

	For the Year Ended December, 31	
	2021	**2020**
Revenues	$ 104,037,710	$ 89,061,010
Costs of revenues	64,232,469	51,900,823
Gross profit	$ 39,805,241	$ 37,160,187
Gross profit margin %	38%	42%

Gross profit increased by $2,645,054, or approximately 7%, to $39,805,241 for the year ended December 31, 2021 from $37,160,187 for the year ended December 31, 2020. Gross profit margin decreased from 42% for the year ended December 31, 2020 to 38% for the year ended December 31, 2021. The higher gross profit margin in fiscal 2020 was mainly attributable to much higher selling price and gross margin for medical masks as a result of COVID-19 in fiscal year 2020. The price of medical mask fell back to normal level as a result of increased supply in fiscal 2021, which brought down the overall gross profit margin.

Operating costs and expenses

Our operating costs and expenses consist of selling expenses, general and administrative expenses and research and development expenses.

Selling

The following table sets forth a breakdown of the selling expenses of the Company:

Years Ended December 31, 2021 and 2020

	2021	**2020**
Transportation expenses	$ 2,802,680	$ 2,473,655
Salaries and benefits	1,287,436	1,110,441
Entertainment expenses	786,226	869,591
Conference expenses	774,298	805,832
Travel allowance	341,165	266,518
Auto expenses	168,832	191,860
Advertising expenses	21,498	53,770
Market research	-	579,357
Other expenses	275,666	273,308
Total	$ 6,457,801	$ 6,624,332

Selling expenses decreased by $166,531, or approximately 3%, to $6,457,801 for the year ended December 31, 2021 from $6,624,332 for the year ended December 31, 2020. The decrease was mainly attributable to the combined effects of the followings:

(a) Our market research expenses decreased by $579,357 to nil for the year ended December 31, 2021 from $579,357 for the year ended December 31, 2020. The decrease was mainly attributable to that the market research conducted in fiscal year 2020 were still valid in fiscal year 2021 and therefore did not conduct additional market research in fiscal 2021.

(b) Our transportation expenses increased by $329,025, or approximately 13%, to $2,802,680 for the year ended December 31, 2021 from $2,473,655 for the year ended December 31, 2020. The increase was mainly attributable to the increased in sales in fiscal year 2021.

(c) Our salaries and benefits expenses increased by $176,995 or approximately 16%, to $1,287,436 for the year ended December 31, 2021 from $1,110,441 for the year ended December 31, 2020. The increase was mainly attributable to that the Covid-19 pandemic in China had been brought under control and the local government had canceled the social insurance relief policy.

(d) Our entertainment expenses decreased by $83,365, or approximately 10%, to $786,226 for the year ended December 31, 2021 from $869,591 for the year ended December 31, 2020. The decrease was mainly attributable to that Yangzhou City in PRC had been under lockdown for some period due to the epidemic in fiscal 2021, so the relevant business entertainment expenses were reduced.

General and administrative

General and administrative expenses primarily consist of the following expenses:

Years Ended December 31, 2021 and 2020

	2021	2020
Salaries and benefits	$ 1,227,228	$ 1,062,041
Entertainment expenses	816,196	998,613
Conference fee	510,267	595,217
Auto expense	153,911	192,148
Maintenance expenses	126,650	153,896
Depreciation expenses	147,522	127,174
Travel allowance	118,113	80,179
Office expenses	94,686	115,204
Surtax expenses	655,679	557,522
Amortization expenses	26,951	26,195
Rental expenses	20,349	19,013
Insurance expenses	9,743	8,444
Service expenses	183,647	426,461
Other expenses	270,530	215,463
Total	$ 4,361,472	$ 4,577,570

General and administrative expenses decreased by $216,098, or approximately 5%, to $4,361,472 for the year ended December 31, 2021, from $4,577,570 for the year ended December 31, 2020. The decrease was mainly due to a decrease of $0.2 million service expenses in fiscal year 2021.

Research and development

The following table sets forth a breakdown of the research and development expenses of the Company:

Years Ended December 31, 2021 and 2020

	2021	2020
Sample manufacturing expenses	$ 1,205,437	$ 1,114,789
Salaries and benefits	1,093,717	931,569
Travel allowance	116,266	105,236
Depreciation expenses	8,161	5,642
Design expenses	110,265	125,199
Material expenses	46,103	50,869
Other expenses	145,065	158,755
Total	$ 2,725,014	$ 2,492,059

Research and development expenses increased by $232,955, or approximately 9%, to $2,725,014 for the year ended December 31, 2021, from $2,492,059 for the year ended December 31, 2020. The increase was mainly due to the increase in salaries and benefits expenses which was mainly attributable to that the pandemic in China had been brought under control and the local government had canceled the social insurance relief policy.

Income from operations

As a result of the factors described above, our income from operations increased by $2,794,728, or approximately 12%, to $26,260,954 for the year ended December 31, 2021 from $23,466,226 for the year ended December 31, 2020.

Income tax expense

Provision for income taxes increased by $590,141, or approximately 13%, to $5,278,462 for the year ended December 31, 2021, from $4,688,321 for the year ended December 31, 2020. The increase was mainly due to the increase of profit before provision for income taxes in 2021.

Net income

As a result of the factors described above, our net income increased by $1,904,324, or approximately 10%, to $20,949,579 for the fiscal year ended December 31, 2021 from $19,045,255 for the fiscal year ended December 31, 2020.

B. Liquidity and Capital Resources

Cash Flows and Working Capital

As of December 31, 2022 and 2021, we had cash of $26,736,700, and $8,149,276, respectively. We believe that our current cash, cash to be generated from our operations and access to capital market will be sufficient to meet our working capital needs for at least the next twelve months. We do not have any amounts committed to be provided by our related party. We are also not dependent upon future financing to meet our liquidity needs for the next twelve months. In order to implement our growth strategies, we plan to expand our business. With additional capacity, and varied product offerings, the Company will provide tailored "one-stop" services from wound care, to surgical auxiliary supplies, to disease prevention. To do so, we may need more capital through equity financing to expand our production and meet market demands.

Substantially all of our operations are conducted in China and all of our revenues, expense and cash are denominated in RMB. RMB is subject to the exchange control regulation in China, and, as a result, we may have difficulty in distributing any dividends outside of China due to PRC exchange control regulations which restrict the ability to convert RMB into U.S. Dollars.

Under applicable PRC regulations, foreign-invested enterprises in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, a foreign-invested enterprise in China is required to set aside at least 10% of its after-tax profit every year as its general reserves based on PRC accounting standards until the accumulative amount of such reserves reaches 50% of its registered capital. These reserves can't be distributed as cash dividends. The board of directors of a foreign-invested enterprise has the discretion to allocate a portion of its after-tax profits to staff welfare and bonus funds, which can't be distributed to equity owners except liquidation. Under PRC law, RMB can be converted into U.S. Dollars under the company's "current account" (including dividends, trade and service-related foreign exchange transactions) rather than the "capital account" (including foreign direct investments and loans, without the prior approval of the SAFE).

For retained earnings accrued after such date, the board of directors will declare dividends after taking into account our operations, earnings, financial condition, the demand for cash and availability and other relevant factors. Any declaration, payment and amount of dividends should be subject to our By-laws, charter and applicable Chinese and U.S. state and federal laws and regulations, including the approval from the shareholders of each subsidiary which intends to declare such dividends, if applicable.

We have limited financial obligations dominated in U.S. dollars, thus the foreign currency restrictions and regulations in PRC on the dividends distribution will not have a material impact on the liquidity, financial condition and results of operations of our Company.

Cash Flow Summary

Years Ended December 31, 2022, 2021 and 2020

	2022	2021	2020
Net Cash (Used in) Provided by Operating Activities	$ (9,163,038)	$ (54,663)	$ 5,325,996
Net Cash Used in Investing Activities	(8,620,292)	(833,817)	(16,094,404)
Net Cash Provided by Financing Activities	37,245,500	1,860,234	1,706,750
Effect of Exchange Rate Changes on Cash	(874,746)	(9,812)	218,137
Cash at Beginning of Year	8,149,276	7,187,334	16,030,855
Cash at End of Year	$ 26,736,700	$ 8,149,276	$ 7,187,334

We had a balance of cash of $26,736,700, $8,149,276 and $7,187,334, respectively as of December 31, 2022, 2021, and 2020.

Years Ended December 31, 2022 and 2021

Cash Flow in Operating Activities

Net cash used in operating activities was $9,163,038 for the year ended December 31, 2022, compared to net cash used in operating activities of $54,663 for the year ended December 31, 2021, representing a $9,108,375, or a 16,663% increase, in the net cash inflow used in operating activities. The increase in net cash used in operating activities was primarily due to the following:

a) Change in bank acceptance receivables was approximately $4.3 million net cash outflow for the year ended December 31, 2022. For the year ended December 31, 2021, change in bank acceptance receivables was approximately $6.5 million net cash outflow, which led to approximately $2.2 million decrease in net cash outflow from operating activities;

b) Change in accounts receivable was approximately $7.1 million net cash outflow for the year ended December 31, 2022. For the year ended December 31, 2021, change in accounts receivable was approximately $20.1 million net cash outflow, which led to approximately $12.9 million decrease in net cash outflow from operating activities;

c) Change in accounts payables was approximately $3.4 million net cash inflow for the year ended December 31, 2022. For the year ended December 31, 2021, change in accounts payables was approximately $4.9 million net cash outflow, which led to approximately $8.3 million increase in net cash inflow from operating activities;

d) Change in taxes payable was approximately $0.8 million net cash inflow for the year ended December 31, 2022. For the year ended December 31, 2021, change in taxes payable was approximately $0.3 million net cash outflow, which let to approximately $1.1 million increase in net cash inflow from operating activities;

e) Write-off of the Tai He deposit resulted in approximately $4.8 million and $nil net cash outflow for the year ended December 31, 2022 and 2021, respectively, which led to an approximately $4.8 million increase in net cash outflow from operating activities. During the IPO, the Company entered into a series of agreements (the "Agreements") with Tai He International Group Limited ("Tai He"), a Hong Kong investment company. Pursuant to the Agreements, Tai He agreed to invest a minimum of $35 million in the IPO subject to the Company making a $7.0 million refundable deposit and advancing a $3.0 million service fee for investor relations and other services payable to Tai He. The Company paid an approximately $4.8 million deposit and $2.3 million service fee to Tai He in 2022. The Company's affiliates and individual shareholders paid the rest of the agreed amount. Later the Company learned that Tai He did not invest in the IPO or provide services to the Company related to the IPO. The Company is now proactively working to terminate the Tai He Agreements and recover the amount paid to Tai He by the Company. Due to the uncertainty of collection, the Company has written off the approximately $4.8 million deposit and fully expensed the $2.3 million service fee paid by the Company to Tai He in the year ended December 31, 2022.

f) Net cash used in operating activities for the year ended December 31, 2022 consisted of net income of approximately $6.2 million, noncash adjustments of approximately $5.1 million. Net cash used in operating activities for the year ended December 31, 2021 consisted of net income of approximately $20.9 million, noncash adjustments of approximately $0.6 million

Cash Flow in Investing Activities

Net cash used in investing activities was $8,620,292 for the year ended December 31, 2022. It consisted of purchases of property and equipment of $2,698,729, long term investment acquisition of $5,944,709 and proceeds from disposal of fixed assets of $23,146.

Net cash used in investing activities was $833,817 for the year ended December 31, 2021. It consisted of purchases of property and equipment of $850,231 and proceeds from disposal of fixed assets of $16,414.

Cash Flow in Financing Activities

For the year ended December 31, 2022, the Company had net cash provided by financing activities of $37,245,500, which consisted of the proceeds from short-term bank loans of $7,579,135, repayments of short-term bank loans of $6,241,641, proceeds from long-term bank loans of $743,052, capital contributed by non-controlling shareholders of $635,310 and proceeds from IPO of $34,529,644.

For the year ended December 31, 2021, the Company had net cash provided by financing activities of $1,860,234, which consisted of the proceeds from short-term bank loans of $6,510,820, and repayments of short-term bank loans of $4,650,586.

Years Ended December 31, 2021 and 2020

Cash Flow in Operating Activities

Net cash used in operating activities was $54,663 for the year ended December 31, 2021, compared to net cash generated from operating activities of $5,325,996 for the year ended December 31, 2020, representing a $5,380,659, or a 101% decrease, in the net cash inflow generated from operating activities. The decrease in net cash generated from operating activities was primarily due to the following:

a) Change in bank acceptance receivables was approximately $6.5 million net cash outflow for the year ended December 31, 2021. For the year ended December 31, 2020, change in bank acceptance receivables was approximately $5.8 million net cash outflow, which led to approximately $0.8 million increase in net cash outflow from operating activities;

b) Change in accounts receivable was approximately $20.1 million net cash outflow for the year ended December 31, 2021. For the year ended December 31, 2020, change in accounts receivable was approximately $13.6 million net cash outflow, which led to approximately $6.5 million increase in net cash outflow from operating activities;

c) Change in due from related party was approximately $0.4 million net cash inflow for the year ended December 31, 2021. For the year ended December 31, 2020, change in due from related party was approximately $0.2 million net cash outflow, which led to approximately $0.6 million increase in net cash inflow from operating activities;

d) Change in inventories was approximately $0.1 million net cash inflow for the year ended December 31, 2021. For the year ended December 31, 2020, change in inventory was approximately $0.2 million net cash outflow, which let to approximately $0.3 million decrease in net cash outflow from operating activities; and

e) Change in deferred IPO costs and other current assets was approximately $0.9 million net cash outflow for the year ended December 31, 2021. For the year ended December 31, 2020, change in deferred IPO costs and other current assets was approximately $0.4 million net cash outflow, which led to approximately $0.5 million increase in net cash outflow from operating activities.

Cash Flow in Investing Activities

Net cash used in investing activities was $833,817 for the year ended December 31, 2021. It consisted of purchases of property and equipment of $850,231 and proceeds from disposal of fixed assets of $16,414.

Net cash used in investing activities was $16,094,404 for the year ended December 31, 2020. It consisted of payments for long-term deposits for building of $12,311,347, purchases of property and equipment of $3,808,259 and proceeds from disposal of fixed assets of $25,202.

Cash Flow in Financing Activities

For the year ended December 31, 2021, the Company had net cash provided by financing activities of $1,860,234, which consisted of the proceeds from short-term bank loans of $6,510,820, and repayments of short-term bank loans of $4,650,586.

For the year ended December 31, 2020, the Company had net cash provided by financing activities of $1,706,750, which consisted of the proceeds from short-term bank loans of $4,359,665, the proceeds from subscriptions receivable of $1,272,232, and repayments of short-term bank loans of $3,925,147.

Off-Balance Sheet Arrangements

As of December 31, 2022 and 2021, there were no off-balance sheet arrangements.

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

Please see Item 4.A. “Information on the Company—Business Overview—Intellectual Property,” above.

D. Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events for the year ended December 31, 2022 that are reasonably likely to have a material adverse effect on our net revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

E. Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements. These financial statements are prepared in accordance with U.S. GAAP, which requires us to make estimates and assumptions that affect the reported amounts of our assets and liabilities and revenue and expenses, to disclose contingent assets and liabilities on the date of the consolidated financial statements, and to disclose the reported amounts of revenue and expenses incurred during the financial reporting period. The most significant estimates and assumptions include the collection of accounts receivable, the useful lives and impairment of our long-lived assets, and the provisions for income taxes. We continue to evaluate these estimates and assumptions that we believe to be reasonable under the circumstances. We rely on these evaluations as the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from those estimates. Some of our accounting policies require higher degrees of judgment than others in their application. We believe critical accounting policies as disclosed in this report reflect the more significant judgments and estimates used in preparation of our consolidated financial statements. We believe there have been no material changes to our critical accounting policies and estimates.

A full list of our critical accounting estimates is included in Note 2 of our consolidated financial statements included elsewhere in this report.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported and disclosed in the consolidated financial statements and related notes.

The most significant estimates and judgments include allowance for bad debts, the valuation of inventory, useful life of property, plant and equipment and income taxes related to realization of deferred tax assets and uncertain tax position. Actual amounts could differ from those estimates.

Fair Value Measurement

Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact, and it considers assumptions that market participants would use when pricing the asset or liability.

The Company adopted the guidance of Accounting Standards Codification ("ASC") 820 for fair value measurements which clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.

Level 2: Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.

Level 3: Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

Cash

Cash consists of petty cash on hand and cash held in banks, which are highly liquid and are unrestricted as to withdrawal or use.

Bank Acceptance Receivables

Bank acceptance receivables are issued by bank under the request of the Company's customers, to pay for the purchased goods. The Company can choose to hold acceptance notes until maturity and receive the face value payment from the bank, or sell (exchange) the acceptance notes at a discount to another party willing to wait until maturity to receive the bank's promised payment. The maturity date of the receivables is all within one year of the original issuance date and carried at face value. The Company is not lending money, it just sells goods to the customers (customers can pay the purchased goods by cash, accounts receivable or bank acceptance receivables). The receivables mature within one year and are non-interest bearing. As bank acceptance receivables are issued by the banks, payments are guaranteed.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable represent trade receivables and are recognized initially at fair value and subsequently adjusted for any allowance for doubtful accounts or impairment.

The Company records impairment losses for accounts receivable based on assessments of the recoverability of the trade and other receivables and individual account analysis, including the current creditworthiness and the past collection history of each debtor. Impairments arise when there is objective evidence indicating that the balances may not be collectible. The identification of bad and doubtful debts, in particular of a loss event, requires the use of judgment and estimates, which involve the estimates of specific losses on individual exposures, as well as a provision on historical trends of collections. Based on management of customers' credit and ongoing relationship, management makes conclusions whether any balances outstanding at the end of the period will be deemed non-collectible on an individual basis and on aging analysis basis. The provision is recorded against accounts receivables balances, with a corresponding charge recorded in the consolidated statements of operations and comprehensive income. Delinquent account balances are written-off against the allowance for doubtful accounts after management has determined that the likelihood of collection is not probable.

Inventories

Inventories are valued using the lower of cost or net realizable value. Cost is principally determined using the weighted-average method. The Company records adjustments to inventory for excess quantities, obsolescence, or impairment, when appropriate, to reflect inventory at net realizable value. These adjustments are based upon a combination of factors including current sales volume, market conditions, lower of cost or market analysis and expected realizable value of the inventory.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth certain information regarding our directors and senior management, as well as employees upon whose work we are dependent, as of the date of this Annual Report.

Directors and Executive Officers	Age	Position/Title
Yongjun Liu	65	Chairman of the board of directors
Xin Wang	34	Chief Executive Officer and Director
Lianzhang Zhao	55	Chief Financial Officer
Xiaoming E	61	Independent Director
Huijuan Zhao	34	Independent Director
Wenzhang Jia	57	Independent Director

The following is a brief biography of each of our executive officers and directors:

Yongjun Liu - Chairman of the board of directors

Mr. Liu, aged 64, has been our Company's Chairman of the board of directors since October, 2020, Chairman and General Manager of Kang Fu International Medical since October 2015, Chairman and General Manager of Yangzhou Huada since December 2001, Chairman and General Manager of Jiangsu Huadong since November 2000, and Chairman and General Manager of Jiangsu Yada since December 1990. In October 2015, Mr. Liu co-founded Kang Fu International Medical with several other co-founders, In December 2001, November 2000 and December 1990, he founded Yangzhou Huada, Jiangsu Huadong and Jiangsu Yada, respectively.

From October 1998 to present, Mr. Liu has been the Chairman of Yangzhou Medical Device Industry Association and Chamber of Commerce and Industry of Touqiao County. From November 2013 to present, Mr. Liu is the Deputy to The People's Congress of Guangling district, Yangzhou City. In December 2018, Mr. Liu was awarded the "Outstanding Entrepreneurs of Guangling District" in Yangzhou. Mr. Liu is a successful entrepreneur with over 40 years' experience in the medical device industry. Mr. Liu is a successful entrepreneur with over 40 years of experience in the medical device industry. He has been awarded as Excellent Entrepreneur, Honest Entrepreneur Representative and Medical Device Industry Representative many times. Mr. Liu participates in philanthropic activities, including public welfare undertakings and has sponsored various impactful undertakings, such as road reconstruction in towns and villages, donations to the Red Cross Society, reconstruction of nursing homes, poverty alleviation, and aid for students.

As the founder of the Company and based on his extensive experience in the medical device industry, we believe that Mr. Liu is qualified to serve as a director.

Xin Wang – Chief Executive Officer and Director

Mr. Xin Wang has been our Chief Executive Officer and Director since December 1, 2022. Prior to his appointment as CEO and director of MHUA, from 2021 to 2022, Mr. Wang was CEO of the Jiangsu Yada. In addition, Mr. Wang served as Vice General Manager of Shanghai New Asia (Group) Co., Ltd., a pharmaceutical company, where he led production management, market expansion, research and development of proprietary Chinese traditional medicines from 2020 to 2021. From 2018 to 2020, Mr. Wang held a key position at Panda Group, Inc., a franchise restaurant corporation based in California, where he was in charge of large commercial projects related to expanding its business operations and upgrading its brand strategy in the U.S. market. In addition, Mr. Wang previously worked as a financial analyst at Morgan Stanley and an area manager at Citibank, N.A., thus providing him insight into global investment banking and U.S. financial markets. Mr. Wang obtained his bachelor's degree from the University of California Santa Barbara, where he double majored in Financial Mathematics & Statistics Analysis and Computer Science. He also obtained his master's degree in Actuarial Science in 2012 from University of California Santa Barbara.

We believe that Mr. Wang is qualified to serve as our CEO and a director because of his extensive knowledge and management experience in the area of the financial market and his experience in the pharmaceutical industry.

Lianzhang Zhao– Chief Financial Officer

Mr. Lianzhang Zhao has been our Chief Financial Officer since December 1, 2022. Prior to his appointment as CFO of MHUA, Mr. Lianzhang Zhao was a Senior Partner at Yangzhou Hanrui Accounting Firm, a PRC accounting firm, from 2013 to 2022. Prior to that, from 2000 to 2013, Mr. Zhao served as the chief financial officer of Yangzhou Guolian Garment Factory Co., which is a Sino-U.S. joint venture company in China. Mr. Zhao is a certified public accountant ("CPA") in China, allowing him to draw on his diverse financial accounting experience across multiple international markets to support MHUA's financial reporting matters. Mr. Zhao received his bachelor's degree in Financial Accounting and Economic Management in 1990 from Yangzhou University.

We believe that Mr. Zhao is qualified to serve as our CFO because of his expertise as a CPA and his extensive knowledge and experience in the financial industry.

Xiaoming E – Independent Director

Mr. E, aged 60, has been a director of our Company since February 15, 2022. From January 2010 to present, he has served as Chairman and General Manager of Jiangsu Changfeng Medical Industry Co., Ltd. From May 2004 to present, he has been Vice Chairman of the Yangzhou Guangling District Medical Device Industry Association. From July 1998 to May 2004, he served as Vice Chairman of Yangzhou Sanitary Product Association. He earned a college degree from Yangzhou Education College in economic management in March 2004.

We believe that Mr. E is qualified to serve as a director because of his experience in the medical device industry.

Huijuan Zhao – Independent Director

Ms. Huijuan Zhao has been a director of our Company since December 1, 2022. Ms. Huijuan Zhao served as a member of the management team at Ping'An Bank, where she oversaw services for high net wealth clients and risk control practices from 2019 to 2022. In her prior role as head of marketing and risk control operations at two Jiangsu-based privately owned businesses operating in the business and financial service sectors, positions she held from 2013 to 2019, Ms. Zhao helped build out market expansion and risk control protocols and playbook and played critical supervisory and coaching roles to the growth and expansion of both businesses. She holds a bachelor's degree in Financial English from Suzhou University, which she received in 2012.

We believe that Ms. Zhao is qualified to serve as director because of her experience in risk control practice. We believe she can provide valuable guidance and oversight to the Company.

Wenzhang Jia – Independent Director

Mr. Wenzhang Jia, aged 56, has been a director of our Company, and the chairman of our audit committee, since June 10, 2022. Mr. Jia is the chairman and chief financial officer of Jiangsu Xibei Electronic Network Co., a company that produces and sells wire and cable, cable TV equipment and network communications equipment, a position he has served in since February of 2000. Mr. Jia received his Bachelor's degree in finance in 2004 from Yangzhou Institute of Commerce and Industry and pursued post-graduate studies in business administration at Tsinghua University in 2007. Mr. Jia has been president of the Yangzhou Electrical Appliance Industry Association since 2007.

As a result of Mr. Jia's knowledge and experience in business and finance, we believe Mr. Jia is qualified to serve as a director on our board of directors and will provide us with valuable oversight and guidance.

Board Diversity

The table below provides certain information regarding the diversity of our board of directors as of the date of this Annual Report.

Board Diversity Matrix				
Country of Principal Executive Offices:	China			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	5			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	4	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	0			
LGBTQ+	0			
Did Not Disclose Demographic Background	0			

Family Relationships

None of our directors or executive officers has a family relationship as defined in Item 401 of Regulation S-K.

Controlled Company

Mr. Yongjun Liu, our chairman of the board of directors, currently beneficially owns approximately 66.56% of the aggregate voting power of our outstanding Ordinary Shares. As a result, we are a "controlled company" within the meaning of the Nasdaq listing rules. As a controlled company, we are permitted to elect to rely on certain exemptions from the obligations to comply with certain corporate governance requirements, including:

- the requirement that a majority of the board of directors consist of independent directors;
- the requirement that our director nominees be selected or recommended solely by independent directors; and
- the requirement that we have a nominating and corporate governance committee and a compensation committee that are composed entirely of independent directors with a written charter addressing the purposes and responsibilities of the committees.

Although we do not intend to rely on the controlled company exemptions under the Nasdaq listing rules even if we are a controlled company, we could elect to rely on these exemptions in the future, and if so, you would not have the same protection afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

B. Compensation

Set forth below is the compensation paid during the fiscal year ended December 31, 2022 to each of our executive officers and directors:

Name	2022 Compensation
Yongjun Liu	$ 50,020
Xin Wang (2)	$ 27,547
Yulin Wang (2)	37,261
Lianzhang Zhao (2)	4,350
Tongying Zhang (1)	$ --
Xiaoming E	11,599
Huijuan Zhao (3)	3,625
Wenzhang Jia	--

(1) The Company had entered into an acting CFO agreement with Cheng Du Milly Bay Consultant Ltd. ("Milly Bay"), pursuant to which Tongying Zhang was assigned by Milly Bay to act as CFO of the Company and the compensation was paid to Milly Bay. Tongying Zhang resigned from her position as our CFO on April 26, 2022. Since that time, Yulin Wang, our then CEO and director, has served as our Interim CFO.

(2) Following the November 30, 2022 conclusion of the Company's employment contract with Mr. Yulin Wang, the Company appointed Mr. Xin Wang to serve as the Company's CEO and Mr. Lianzhang Zhao as the Company's CFO since December 1, 2022.

(3) On November 30, 2022, Mr. Xu Han resigned from his position as a member of the board of directors due to personal reasons. On December 1, 2022, the Company appointed Ms. Huijuan Zhao to serve as an independent member of our board of director.

C. Board Practices

Term of Office

Our directors are each appointed for a one-year term to hold office until the next annual general meeting of our shareholders or until removed from office in accordance with our articles of association.

Employment Agreement with our Chief Executive Officer and Chief Financial Officer

Following the November 30, 2022 conclusion of the Company's employment contract with Mr. Yulin Wang, who had served as the Company's CEO and interim CFO, effective December 1, 2022, the Company appointed Mr. Xin Wang to serve as the Company's CEO and a director and Mr. Lianzhang Zhao to serve as the Company's CFO.

In conjunction with his appointment as CEO of MHUA, Mr. Wang entered into a three-year employment agreement with MHUA. In conjunction with his appointment as CFO of MHUA, Mr. Zhao entered into an employment agreement with MHUA.

Directors Service Contracts

On February 18, 2022, we entered into Director Service Agreements (the "Agreements") with each of our independent directors, Xiaoming E, Xu Han (who resigned from his position as an independent director since November 30, 2022) and Heung Ming Wong (whose service terminated on June 10, 2022). The Agreements each feature a one-year term with annual renewals. Mr. E and Mr. Han would each receive a monthly stipend of ¥8,000 (approximately $1,265) per month during their terms of service. Mr. Wong, who served as the Chairman of the Audit Committee of the board of directors, received a monthly stipend of $2,500 per month during his term of service. In addition, Mr. Wong received options to purchase 1,000 Ordinary Shares of the Company, at an exercise price of $8.90 per share, representing a value of $10,000, as determined by reference to the Company's IPO price. The options were to vest in equal monthly installments over Mr. Wong's initial year of service and were exercisable for a term of ten years. Upon annual renewals of his service agreement, Mr. Wong was to receive additional options valued at $10,000, with the number of options granted to be determined with reference to the volume weighted average price for the Company's Ordinary Shares during the thirty (30) trading days preceding the annual renewal date. We entered into a similar agreement with Mr. Jia following his appointment to the board of directors, and as chair of the Audit Committee, on June 28, 2022, pursuant to which Mr. Jia received $10,000, or 1,886, of our Ordinary Shares, exercisable at $5.30 per share, which was the closing price of our Ordinary Shares on the date of grant and which options vest in substantially equal monthly installments over a period of 12 months. Mr. Jia also receive a cash fee of $2,500 per month during his term of service.

On December 1, 2022, in conjunction with her appointment as a director, Ms. Zhao entered into a letter agreement with the Company outlining the terms of her service as a director. Ms. Zhao, who serves as a member of audit committee and the chairwoman of the nominating committee, will receive a monthly stipend of $2,500 per month during her term of service. In addition, Ms. Zhao will receive stock options to purchase 740 of the Company's Ordinary Shares, par value $0.0005 per share, at an exercise price of $13.51. The options will vest and become exercisable in equal monthly installments over the course of Ms. Zhao's initial year of service, that is over a 12 month period.

Committees of the Board

We have established and will maintain three committees under the board of directors: an audit committee, a compensation committee, and a nominating and corporate governance committee. We have adopted the charter for each of the three committees. Each committee's members and functions are described below.

Audit Committee. Our audit committee consists of Wenzhang Jia, Xiaoming E and Huijuan Zhao, and is chaired by Mr. Jia. Wenzhang Jia, Xiaoming E and Huijuan Zhao each satisfies the "independence" requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq Stock Market and meets the independence standards under Rule 10A-3 under the Exchange Act. We have determined that Wenzhang Jia qualifies as an "audit committee financial expert." The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee is responsible for, among other things:

- selecting the independent registered public accounting firm and pre-approving all auditing and non-auditing services permitted to be performed by the independent registered public accounting firm;
- reviewing with the independent registered public accounting firm any audit problems or difficulties and management's response;
- reviewing and approving all proposed related party transactions, as defined in Item 404 of Regulation S-K under the Securities Act;
- discussing the annual audited financial statements with management and the independent registered public accounting firm;
- reviewing major issues as to the adequacy of our internal controls and any special audit steps adopted in light of material control deficiencies;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately and periodically with management and the independent registered public accounting firm; and
- reporting regularly to the board of directors.

Compensation Committee. Our compensation committee consists of Wenzhang Jia, Xiaoming E and Huijuan Zhao, and is chaired by Huijuan Zhao. The compensation committee will assist the board of directors in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers. Our chief executive officer may not be present at any committee meeting during which his compensation is deliberated upon. The compensation committee is responsible for, among other things:

- reviewing the total compensation package for our executive officers and making recommendations to the board of directors with respect to it;
- reviewing the compensation of our non-employee directors and making recommendations to the board of directors with respect to it; and
- periodically reviewing and approving any long-term incentive compensation or equity plans, programs or similar arrangements, annual bonuses, and employee pension and welfare benefit plans.

Nominating Committee. Our nominating committee consists of Wenzhang Jia, Xiaoming E and Huijuan Zhao, and is chaired by Huijuan Zhao. The nominating committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board of directors and its committees. The nominating committee is responsible for, among other things:

- recommending nominees to the board of directors for election or re-election to the board of directors, or for appointment to fill any vacancy on the board of directors;

- reviewing annually with the board of directors the current composition of the board of directors with regards to characteristics such as independence, age, skills, experience and availability of service to us;

- selecting and recommending to the board of directors the names of directors to serve as members of the audit committee and the compensation committee, as well as of the nominating committee itself; and

- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Duties of Directors

Under Cayman Islands law, our directors owe fiduciary duties to our company, including a duty of loyalty, a duty to act honestly, and a duty to act in a manner they consider in good faith to be in our best interests. Our directors must also exercise their powers only for a proper purpose. Our directors also owe to our company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended and restated from time to time. We have the right to seek damages if a duty owed by our directors is breached. In limited exceptional circumstances, a shareholder may have the right to seek damages in our name if a duty owed by our directors is breached.

Terms of Directors

Our directors may be elected by a resolution of our board of directors, or by an ordinary resolution of our shareholders. Our directors are not subject to a term of office and hold office until such time as they are removed from office by ordinary resolution of the shareholders. A director will cease to be a director if, among other things, the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found by our company to be or becomes of unsound mind, (iii) resigns his office by notice in writing to the company, or (iv) without special leave of absence from our board of directors, is absent from three consecutive board meetings and our directors resolve that his office be vacated.

Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to our directors, officers and employees. A copy of this code is available on our website. We intend to disclose on our website any amendments to the Code of Business Conduct and Ethics and any waivers of the Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions.

D. Employees

Employees

We had 626, 622 and 647 full-time employees as of December 31, 2022, 2021 and 2020, respectively. The following table sets forth the number of full-time employees based on category of employment and place of employment as of December 31, 2022:

Function/Department	Yangzhou Huada	Jiangsu Huadong	Jiangsu Yada
Management	12	33	39
Sales and Marketing	9	36	36
Research and Development	0	41	37
Production	68	95	220
Subtotal Total	89	205	332
Total		**626**	

Our success depends on our ability to attract, motivate, train and retain qualified personnel. We believe we offer our employees competitive compensation packages and an environment that encourages self-development and, as a result, have generally been able to attract and retain qualified personnel and maintain a stable core management team.

As required by laws and regulations in China, we participate in various employee social security plans that are organized by municipal and provincial governments including, among other things, pension, medical insurance, unemployment insurance, maternity insurance, on-the-job injury insurance and housing fund plans through a PRC government-mandated benefit contribution plan. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses and certain allowances of our employees, up to a maximum amount specified by the local government from time to time.

We believe we maintain a good working relationship with our employees, and we have not experienced any material labor disputes. None of our employees is represented by a labor union.

E. Share Ownership

The following table sets forth, as of the date of this report, the beneficial ownership of our Ordinary Shares by each executive officer and director, by each person known by us to beneficially own more than 5% of our Ordinary Shares and by the executive officers and directors as a group. Except as otherwise indicated, all shares are owned directly and the percentage shown is based on 23,940,000 shares of Ordinary Shares issued and outstanding.

Title of class	Name of beneficial owner	Amount of beneficial ownership	Percent of class
Current Executive Officers and Directors			
Ordinary Shares	Yongjun Liu[1]	15,935,000	66.56%
Ordinary Shares	Xin Wang	-	-%
Ordinary Shares	Lianzhang Zhao	-	-
Ordinary Shares	Tongying Zhang	-	-%
Ordinary Shares	Xiaoming E	-	-%
Ordinary Shares	Huijuan Zhao[3]	740	-%
Ordinary Shares	Wenzhang Jia[2]	1,886	-%
Total of All Current Officers and Directors:		**15,936,886**	**66.56%**
≥ 5% Beneficial Owners			
None.			

(1) Mr. Liu holds these shares through Bright Accomplish Limited, a holding company controlled jointly by Mr. Liu and his wife, Yin Liu.

(2) Represents options to purchase 1,886 Ordinary Shares of the Company, at an exercise price of $5.30 per share. The options vest in equal monthly installments over Mr. jia's initial year of service and are exercisable for a term of ten years. As of the date of this report, no options are vested.

(3) Represents options to purchase 740 Ordinary Shares of the Company, at an exercise price of $13.51 per share. The options vest in equal monthly installments over Ms. Zhao's initial year of service and are exercisable for a term of ten years. As of the date of this report, no options are vested.

As used in this table, "beneficial ownership" means the sole or shared power to vote, or to direct the voting of, a security, or the sole or shared investment power with respect to a security (i.e., the power to dispose of, or to direct the disposition of, a security). In addition, for purposes of this table, a person is deemed, as of any date, to have "beneficial ownership" of any security that such person has the right to acquire within 60 days after such date.

The persons named above have full voting and investment power with respect to the shares indicated. Under the rules of the Securities and Exchange Commission, a person (or group of persons) is deemed to be a "beneficial owner" of a security if he or she, directly or indirectly, has or shares the power to vote or to direct the voting of such security, or the power to dispose of or to direct the disposition of such security. Accordingly, more than one person may be deemed to be a beneficial owner of the same security. A person is also deemed to be a beneficial owner of any security, which that person has the right to acquire within 60 days, such as options or warrants to purchase our Ordinary Shares.

Major Shareholders

Other than as set forth above, there are no beneficial owners of 5% or more of our voting securities. The company is not directly or indirectly owned or controlled by another corporation(s) or by any foreign government. There are no arrangements, known to us, the operation of which may at a subsequent date result in a change in control of the company.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

See Item 6 "Directors, Senior Management and Employees—E. Share Ownership."

B. Related Party Transactions

Except for the transactions set forth below, during our preceding three financial years up to the date of this report, there have been no transactions or loans between the company and (a) enterprises that directly or indirectly through one or more intermediaries, control or are controlled by, or are under common control with, the company; (b) associates; (c) individuals owning, directly or indirectly, an interest in the voting power of the company that gives them significant influence over the company, and close members of any such individual's family; (d) key management personnel, that is, those persons having authority and responsibility for planning, directing and controlling the activities of the company, including directors and senior management of companies and close members of such individuals' families; and (e) enterprises in which a substantial interest in the voting power is owned, directly or indirectly, by any person described in (c) or (d) or over which such a person is able to exercise significant influence.

Transaction with Yangzhou Meihua Import and Export Co., Ltd.

We sell products at market price to Yangzhou Meihua Import and Export Co., Ltd., an affiliate controlled by Kai Liu, the son of Yongjun Liu, our Chairman and shareholder. For the fiscal years ended December 31, 2022 and 2021, the sales amount was $18,780 and $51,750, respectively, and as of December 31, 2022 and December 31, 2021, the amount due from Yangzhou Meihua Import and Export Co., Ltd. both were nil. The main business of Yangzhou Meihua Import and Export Co., Ltd. is the import and export of medical consumables, and the main types of products it purchases from the Company are dressing wounds and wiping wounds, Yang Ke Tou (Suction tube), disposable urinary swab, disposable umbilical cord clamp, disposable suction connection pipe, disposable medical gauze, medical urine cup, medical disinfection dressing surgical kit and round head steel needles.

Transaction with Yangzhou Yada Powder Metallurgy Co., Ltd.

We sell products at market price to Yangzhou Yada Powder Metallurgy Co., Ltd., an affiliate controlled by Kai Liu, the son of Yongjun Liu, our Chairman and shareholder. For the fiscal years ended December 31, 2022 and 2021, the sales amount was $nil and $347,737, respectively, and as of December 31, 2022 and December 31, 2021, the amount due from Yangzhou Yada Powder Metallurgy Co., Ltd. both were nil. The main business of Yangzhou Yada Powder Metallurgy Co., Ltd. is gear and metal accessories processing, and the main types of products it purchases from the Company are One-way seat fittings, Gear 2 accessories, Gear 3 accessories, Steel needle, Crank fittings, Universal joint seat fittings, Cylindrical pin, Axle sleeve, Axle pin and Bevel gear fittings.

Transaction with Shanghai Xinya Pharmaceutical Hanjiang Co., Ltd.

We sell products at market price to Shanghai Xinya Pharmaceutical Hanjiang Co., Ltd., an affiliate controlled by Kai Liu, the son of Yongjun Liu, our Chairman and shareholder. For the fiscal years ended December 31, 2022 and 2021, the sales amount was $10,416 and $176,414, respectively, and as of December 31, 2022 and December 31, 2021, the amount due from Xinya Pharmaceutical Hanjiang Co., Ltd. both were nil. The main business of Shanghai Xinya Pharmacy Hanjiang Co., Ltd. is drug production and sales, and the main types of products it purchases from the Company are oral solid medical high-density polyethylene bottles and disposable masks.

Share Exchange Agreement with Kang Fu International Medical Co., Ltd. and its Shareholders

On December 21, 2020, we entered into a Share Exchange Agreement with Kang Fu International Medical Co., Ltd. ("Kang Fu") and its shareholders, Yongjun Liu (our Chairman and Director) and Yin Liu (his wife). Under the Share Exchange Agreement, we issued a total of 15,933,000 Ordinary Shares to Mr. and Mrs. Liu, and in turn acquired 41,400,000 shares (69%) of Kang Fu from Yongjun Liu and 18,600,000 shares (31%) of Kang Fu from Yin Liu, respectively, resulting in Kang Fu becoming our wholly owned subsidiary. Mr. and Mrs. Liu subsequently transferred the 15,935,000 Ordinary Shares received in this transaction to their holding company, Bright Accomplish Limited.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Financial Statements

We have appended consolidated financial statements filed as part of this report. See Item 18 “Financial Statements.”

Legal Proceedings

See Item 4 –B “Business Overview” above, under “Legal Proceedings.”

Dividend Policy

To date, we have not paid any cash dividends on our shares. As a Cayman Islands company, we may only declare and pay dividends except when the corporation is insolvent or would thereby be made insolvent or when the declaration or payment would be contrary to any restrictions contained in our Articles of Association. Dividends may be declared and paid out of surplus only; but in case there is no surplus, dividends may be declared or paid out of the net profits for the fiscal year in which the dividend is declared and for the preceding fiscal year. We currently anticipate that we will retain any available funds to finance the growth and operation of our business and we do not anticipate paying any cash dividends in the foreseeable future. Additionally, our cash held in foreign countries may be subject to certain control limitations or repatriation requirements, limiting our ability to use this cash to pay dividends.

B. Significant Changes

No significant change has occurred since the date of our consolidated financial statements filed as part of this Annual Report.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares is listed on the Nasdaq Global Market and trade under the symbol “MHUA.”

B. Plan of Distribution

Not applicable.

C. Markets

See our disclosures above under “A. Offer and Listing Details.”

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The following are summaries of material provisions of our memorandum and articles of association and of the Companies Law, insofar as they relate to the material terms of our Ordinary Shares.

Purpose and Objectives of Our Company. Under our amended and restated memorandum and articles of association, the purpose and objectives of our company are unrestricted and we have the full power and authority to carry out any objective not prohibited by the law of the Cayman Islands.

Ordinary Shares. Our Ordinary Shares are issued in registered form and are issued when registered in our register of members. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares.

Dividends. The holders of our Ordinary Shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may by ordinary resolution declare a final dividend, but no dividend may exceed the amount recommended by our directors. Our amended and restated articles of association provide that dividends may be declared and paid out of our profits, realized or unrealized, or from any reserve set aside from profits which our board of directors determine is no longer needed. Dividends may also be declared and paid out of share premium account or any other fund or account which can be authorized for this purpose subject to the restrictions of the Companies Act, provided that in no circumstances may we pay a dividend if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business.

Voting Rights. Any action required or permitted to be taken by the shareholders must be taken at a duly called and quorate annual or extraordinary general meeting of the shareholders entitled to vote on such action, or in lieu of a general meeting, be effected by a resolution in writing. On a show of hands each shareholder is entitled to one vote or, on a poll, each shareholder is entitled to one vote for each Ordinary Share, voting together as a single class, on all matters that require a shareholder's vote. Voting at any shareholders' meeting is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or one or more shareholders present in person or by proxy entitled to vote and who together hold not less than 10 percent of the paid-up voting share capital for the Company.

A quorum required for a meeting of shareholders consists of one or more shareholders present and holding at least a majority of the votes of the issued and outstanding voting shares in our company. Shareholders may be present in person or by proxy or, if the shareholder is a legal entity, by its duly authorized representative. Shareholders' meetings may be convened by our board of directors on its own initiative or upon a request to the directors by shareholders holding no less than 10 percent of our paid voting share capital. Advance notice of at least seven days is required for the convening of our annual general shareholders' meeting and any other general shareholders' meeting.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the Ordinary Shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes cast attaching to the outstanding Ordinary Shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our amended and restated memorandum and articles of association. Holders of the Ordinary Shares may, among other things, divide or combine their shares by ordinary resolution.

Election of directors. Directors may be appointed by an ordinary resolution of our shareholder or by a resolution of the directors of the Company.

Meetings of directors. At any meeting of directors, a quorum will be present if two directors are present, unless otherwise fixed by the directors. If there is a sole director, that director shall be a quorum. A person who holds office as an alternate director shall be counted in the quorum. A director who also acts as an alternate director shall be counted twice towards the quorum. An action that may be taken by the directors at a meeting may also be taken by a resolution of directors consented to in writing by all of the directors.

Transfer of Ordinary Shares. Any of our shareholders may transfer all or any of his or her Ordinary Shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any Ordinary Share whether or not it is fully paid up without assigning any reason for doing so.

If our directors refuse to register a transfer they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers of our Ordinary Shares may be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 45 days in any year as our board of directors may determine.

Liquidation. On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of shares), assets available for distribution among the holders of Ordinary Shares shall be distributed among the holders of our shares on a pro rata basis. If our assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that the losses are borne by our shareholders proportionately.

Calls on Shares and Forfeiture of Shares. Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders at least 14 days prior to the specified time and place of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption of Shares. The Companies Act and our amended and restated articles of association permit us to purchase, redeem or otherwise acquire our own shares, subject to certain restrictions and requirements under the Companies Act, our amended and restated memorandum and articles of association and any applicable requirements imposed from time to time by the Nasdaq, the Securities and Exchange Commission. In accordance with our articles of association and provided the necessary shareholders or board of director approval have been obtained, we may issue shares on terms that are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner, including out of capital, as may be determined by our board of directors. Under the Companies Act, the repurchase of any share may be paid out of our company's profits, out of our share capital account or out of the proceeds of a fresh issue of shares made for the purpose of such repurchase, or, subject to certain conditions, out of capital. If the repurchase proceeds are paid out of our Company's capital, our Company must, immediately following such payment, be able to pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act, no such share may be repurchased (1) unless it is fully paid up, (2) if such repurchase would result in there being no shares outstanding, and (3) unless the manner of purchase (if not so authorized under the amended and restated memorandum and articles of association) has first been authorized by a resolution of our shareholders. In addition, under the Companies Act, our Company may accept the surrender of any fully paid share for no consideration unless, as a result of the surrender, the surrender would result in there being no shares outstanding (other than shares held as treasury shares).

Variations of Rights of Shares. The rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our company is being wound-up, may be varied with the consent in writing of the holders of two-thirds of the issued shares of that class or series or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Changes in the number of shares we are authorized to issue and those in issue. We may from time to time by resolution of shareholders in the requisite majorities:

- increase or decrease the authorized share capital of our Company;
- subdivide our authorized and issued shares into a larger number of shares; and
- consolidate our authorized and issued shares into a smaller number of shares.

Issuance of Additional Shares. Our amended and restated memorandum and articles of association authorizes our board of directors to issue additional Ordinary Shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Inspection of Books and Records. Holders of our Ordinary Shares will have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we will provide our shareholders with annual audited financial statements.

Preferred Shares

As at the date of this report, we have not issued any preferred shares. Under the amended and restated articles of association, before any Preferred Shares of any series are issued, our directors shall fix, by resolution of directors, the following provisions of such series:

- the designation of such series and the number of Preferred Shares to constitute such series;
- whether the shares of such series shall have voting rights, in addition to any voting rights provided by Companies Act, and, if so, the terms of such voting rights, which may be general or limited;
- the dividends, if any, payable on such series, whether any such dividends shall be cumulative, and, if so, from what dates, the conditions and dates upon which such dividends shall be payable, the preference or relation which such dividends shall bear to the dividends payable on any Shares of any other class of Shares or any other series of Preferred Shares;
- whether the Preferred Shares or such series shall be subject to redemption by the Company, and, if so, the times, prices and other conditions of such redemption;
- the amount or amounts payable upon Preferred Shares of such series upon, and the rights of the holders of such series in, a voluntary or involuntary liquidation, dissolution or winding up, or upon any distribution of the assets, of the Company;
- whether the Preferred Shares of such series shall be subject to the operation of a retirement or sinking fund and, if so, the extent to and manner in which any such retirement or sinking fund shall be applied to the purchase or redemption of the Preferred Shares of such series for retirement or other corporate purposes and the terms and provisions relative to the operation of the retirement or sinking fund;
- whether the Preferred Shares of such series shall be convertible into, or exchangeable for, Shares of any other class of Shares or any other series of Preferred Shares or any other securities and, if so, the price or prices or the rate or rates of conversion or exchange and the method, if any, of adjusting the same, and any other terms and conditions of conversion or exchange;
- the limitations and restrictions, if any, to be effective while any Preferred Shares or such series are outstanding upon the payment of dividends or the making of other distributions on, and upon the purchase, redemption or other acquisition by the Company of, the existing Shares or Shares of any other class of Shares or any other series of Preferred Shares;
- the conditions or restrictions, if any, upon the creation of indebtedness of the Company or upon the issue of any additional Shares, including additional shares of such series or of any other class of Shares or any other series of Preferred Shares; and
- any other powers, preferences and relative, participating, optional and other special rights, and any qualifications, limitations and restrictions of any other class of Shares or any other series of Preferred Shares.

Exempted Company

We are an exempted company incorporated with limited liability under the Companies Act of the Cayman Islands. The Companies Act of the Cayman Islands distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that, for an exempted company that does not hold a license to carry on business in the Cayman Islands:

- an exempted company does not have to file an annual return of its shareholders with the Registrar of Companies of the Cayman Islands;
- an exempted company's register of members is not required to be open to inspection;
- an exempted company does not have to hold an annual general meeting;
- an exempted company is prohibited from making any invitation to the public in the Cayman Islands to subscribe for any of its securities;
- an exempted company may not issue negotiable or bearer shares;
- an exempted company may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- an exempted company may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- an exempted company may register as an exempted limited duration company; and
- an exempted company may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on that shareholder's shares of the company.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in Item 4 "Information on the Company," Item 5 "Operating and Financial Review and Prospects—F. Tabular Disclosure of Contractual Obligations," Item 7 "Major Shareholders and Related Party Transactions," or filed (or incorporated by reference) as exhibits to this Annual Report or otherwise described or referenced in this Annual Report.

D. Exchange Controls

Cayman Islands Exchange Controls

There are no material exchange controls restrictions on payment of dividends, interest or other payments to the holders of our Ordinary Shares or on the conduct of our operations in the Cayman Islands, where we were incorporated. There are no material Cayman Islands laws that impose any material exchange controls on us or that affect the payment of dividends, interest or other payments to nonresident holders of our Ordinary Shares. Cayman Islands law and our memorandum and articles of association do not impose any material limitations on the right of non-residents or foreign owners to hold or vote our Ordinary Shares.

PRC Exchange Controls

Regulations on Foreign Currency Exchange

Under the PRC Foreign Currency Administration Rules promulgated on January 29, 1996 and last amended on August 5, 2008 and various regulations issued by SAFE and other relevant PRC government authorities, payment of current account items in foreign currencies, such as trade and service payments, payment of interest and dividends can be made without prior approval from SAFE by following the appropriate procedural requirements. By contrast, the conversion of RMB into foreign currencies and remittance of the converted foreign currency outside the PRC for the purpose of capital account items, such as direct equity investments, loans and repatriation of investment, requires prior approval from SAFE or its local office.

On February 13, 2015, SAFE promulgated the Circular on Simplifying and Improving the Foreign Currency Management Policy on Direct Investment, effective from June 1, 2015, which cancels the requirement for obtaining approvals of foreign exchange registration of foreign direct investment and overseas direct investment from SAFE. The application for the registration of foreign exchange for the purpose of foreign direct investment and overseas direct investment may be filed with qualified banks, which, under the supervision of SAFE, may review the application and process the registration.

The Circular of the SAFE on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise, or SAFE Circular 19, was promulgated on March 30, 2015 and became effective on June 1, 2015. According to SAFE Circular 19, a foreign-invested enterprise may, according to its actual business needs, settle with a bank the portion of the foreign exchange capital in its capital account for which the relevant foreign exchange bureau has confirmed monetary contribution rights and interests (or for which the bank has registered the account-crediting of monetary contribution). For the time being, foreign-invested enterprises are allowed to settle 100% of their foreign exchange capitals on a discretionary basis; a foreign-invested enterprise shall truthfully use its capital for its own operational purposes within the scope of business; where an ordinary foreign-invested enterprise makes domestic equity investment with the amount of foreign exchanges settled, the invested enterprise shall first go through domestic re-investment registration and open a corresponding Account for Foreign Exchange Settlement Pending Payment with the foreign exchange bureau (bank) at the place of registration. The Circular of the SAFE on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts, or SAFE Circular 16, was promulgated and became effective on June 9, 2016. According to SAFE Circular 16, enterprises registered in PRC may also convert their foreign debts from foreign currency into Renminbi on self-discretionary basis. SAFE Circular 16 provides an integrated standard for conversion of foreign exchange under capital account items (including but not limited to foreign currency capital and foreign debts) on self—discretionary basis, which applies to all enterprises registered in the PRC. SAFE Circular 16 reiterates the principle that Renminbi converted from foreign currency-denominated capital of a company may not be directly or indirectly used for purposes beyond its business scope and may not be used for investments in securities or other investment with the exception of bank financial products that can guarantee the principal within the PRC unless otherwise specifically provided. Besides, the converted Renminbi shall not be used to make loans for related enterprises unless it is within the business scope or to build or to purchase any real estate that is not for the enterprise own use with the exception for the real estate enterprise. On October 23, 2019, the SAFE issued the Notice of the State Administration of Foreign Exchange on Further Facilitating Cross-border Trade and Investment, or the SAFE Circular 28, which, among other things, expanded the use of foreign exchange capital to domestic equity investment area. Non-investment foreign-funded enterprises are allowed to lawfully make domestic equity investments by using their capital on the premise without violation to prevailing special administrative measures for access of foreign investments (negative list) and the authenticity and compliance with the regulations of domestic investment projects.

On January 26, 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimizing Genuineness and Compliance Verification, or SAFE Circular 3, which stipulates several capital control measures with respect to the outbound remittance of profits from domestic entities to offshore entities, including (i) banks must check whether the transaction is genuine by reviewing board resolutions regarding profit distribution, original copies of tax filing records and audited financial statements, and (ii) domestic entities must retain income to account for previous years' losses before remitting any profits. Moreover, pursuant to SAFE Circular 3, domestic entities must explain in detail the sources of capital and how the capital will be used, and provide board resolutions, contracts and other proof as a part of the registration procedure for outbound investment.

Regulations on Foreign Exchange Registration of Overseas Investment by PRC Residents

SAFE issued the Circular on Relevant Issues Relating to Domestic Resident's Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, which became effective in July 2014, to replace the Circular of the State Administration of Foreign Exchange on Issues Concerning the Regulation of Foreign Exchange in Equity Finance and Roundtrip Investments by Domestic Residents through Offshore Special Purpose Vehicles, to regulate foreign exchange matters in relation to the use of special purpose vehicles, or SPVs, by PRC residents or entities to seek offshore investment and financing or conduct round trip investment in China. SAFE Circular 37 defines a SPV as an offshore entity established or controlled, directly or indirectly, by PRC residents or entities for the purpose of seeking offshore financing or making offshore investment, using legitimate onshore or offshore assets or interests, while "round trip investment" is defined as direct investment in China by PRC residents or entities through SPVs, namely, establishing foreign-invested enterprises to obtain the ownership, control rights and management rights. SAFE Circular 37 stipulates that, prior to making contributions into an SPV, PRC residents or entities be required to complete foreign exchange registration with SAFE or its local branch. In addition, SAFE promulgated the Notice on Further Simplifying and Improving the Administration of the Foreign Exchange Concerning Direct Investment in February 2015, which amended SAFE Circular 37 and became effective on June 1, 2015, requiring PRC residents or entities to register with qualified banks rather than SAFE in connection with their establishment or control of an offshore entity established for the purpose of overseas investment or financing.

PRC residents or entities who had contributed legitimate onshore or offshore interests or assets to SPVs but had not obtained registration as required before the implementation of the SAFE Circular 37 must register their ownership interests or control in the SPVs with qualified banks. An amendment to the registration is required if there is a material change with respect to the SPV registered, such as any change of basic information (including change of the PRC residents, name and operation term), increases or decreases in investment amount, transfers or exchanges of shares, and mergers or divisions. Failure to comply with the registration procedures set forth in SAFE Circular 37 and the subsequent notice, or making misrepresentation on or failure to disclose controllers of the foreign-invested enterprise that is established through round-trip investment, may result in restrictions being imposed on the foreign exchange activities of the relevant foreign-invested enterprise, including payment of dividends and other distributions, such as proceeds from any reduction in capital, share transfer or liquidation, to its offshore parent or affiliate, and the capital inflow from the offshore parent, and may also subject relevant PRC residents or entities to penalties under PRC foreign exchange administration regulations. See "Risk Factors—Risks Related to Doing Business in China—PRC regulations relating to the establishment of offshore special purpose companies by PRC residents may subject our PRC resident beneficial owners or our PRC subsidiaries to liability or penalties, limit our ability to inject capital into our PRC subsidiaries, limit our PRC subsidiaries' ability to increase its registered capital or distribute profits to us, or may otherwise adversely affect us."

Regulations on Dividend Distribution

Distribution of dividends of foreign investment enterprises are mainly governed by the Foreign Investment Enterprise Law, issued in 1986 and amended in 2000 and 2016 respectively, and the Implementation Rules under the Foreign Investment Enterprise Law, issued in 1990 and amended in 2001 and 2014 respectively. Under these regulations, foreign investment enterprises in the PRC may distribute dividends only out of their accumulative profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, no less than 10% of the accumulated profits of the foreign investment enterprises in the PRC are required to be allocated to fund certain reserve funds each year unless these reserves have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from previous fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year. Under our current corporate structure, our BVI holding company may rely on dividend payments from our wholly foreign-owned enterprise incorporated in China to fund any cash and financing requirements we may have. Limitation on the ability of our operating subsidiaries to make remittance to our WOFEs and on the ability of our WOFEs to pay dividends to us could limit our ability to access cash generated by the operations of those entities.

E. Taxation

The following summary of the material Cayman Islands, PRC and U.S. federal income tax consequences of an investment in our Ordinary Shares is based upon laws and relevant interpretations thereof in effect as of the date of this Annual Report, all of which are subject to change. This summary does not deal with all possible tax consequences relating to an investment in our Ordinary Shares, such as the tax consequences under U.S. state and local tax laws or under the tax laws of jurisdictions other than the Cayman Islands, the People's Republic of China and the United States.

Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to investors levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or, after execution, brought within the jurisdiction of the Cayman Islands. The Cayman Islands is a party to a double tax treaty entered with the United Kingdom in 2010 but is otherwise is not party to any double tax treaties which are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of Ordinary Shares will not be subject to taxation in the Cayman Islands and no withholding will be required under Cayman Islands laws on the payment of a dividend or capital to any holder of Ordinary Shares, nor will gains derived from the disposal of Ordinary Shares be subject to Cayman Islands income or corporation tax.

No stamp duty is payable in the Cayman Islands in respect of the issue of our Ordinary Shares or on an instrument of transfer in respect of our Ordinary Shares except those which hold interests in land in the Cayman Islands.

People's Republic of China Taxation

Under the PRC EIT Law and its implementation rules, an enterprise established outside the PRC with a "de facto management body" within the PRC is considered a resident enterprise and will be subject to the enterprise income tax at the rate of 25% on its global income. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control over and overall management of the business, production, personnel, accounts and properties of an enterprise. In April 2009, the SAT issued the Circular of the SAT on Issues Relating to Identification of PRC-Controlled Overseas Registered Enterprises as Resident Enterprises in Accordance With the De Facto Standards of Organizational Management, or SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" test should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in the PRC only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in the PRC; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (iv) at least 50% of voting board members or senior executives habitually reside in the PRC.

Further to SAT Circular 82, the SAT issued the SAT Bulletin 45, which took effect in September 2011, to provide more guidance on the implementation of SAT Circular 82. SAT Bulletin 45 provides for procedures and administration details of determination on resident status and administration on post-determination matters. Our Company is a company incorporated outside the PRC. As a holding company, its sole asset is its share ownership of its direct subsidiary, a Hong Kong company, and its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside the PRC. As such, we do not believe that our Company meets all of the conditions above or is a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." There can be no assurance that the PRC government will ultimately take a view that is consistent with us. If the PRC tax authorities determine that our Cayman Islands holding company is a PRC resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. For example, a 10% withholding tax would be imposed on dividends we pay to our non-PRC enterprise shareholders. In addition, nonresident enterprise shareholders may be subject to PRC tax on gains realized on the sale or other disposition of Ordinary Shares, as if such income is treated as sourced from within the PRC. Furthermore, if we are deemed a PRC resident enterprise, dividends paid to our non-PRC individual shareholders and any gain realized on the transfer of Ordinary Shares by such shareholders may be subject to PRC tax at a rate of 20% (which, in the case of dividends, may be withheld at source by us). These rates may be reduced by an applicable tax treaty, but it is unclear whether in practice non-PRC shareholders of our Company would be able to obtain the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. See "Risk Factors—Risks Related to Doing Business in China—If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders."

Notwithstanding the foregoing, our PRC subsidiaries, Jiangsu Huadong enjoy preferential income tax rate of 15% until December 31, 2021, due to its treatment as "National High-Tech Enterprises" in China. Prior to the expiration date of such treatment, it may submit applications for renewal and continue enjoying the preferential income tax rate if granted.

United States Federal Income Taxation Considerations

The following discussion is a summary of United States federal income tax considerations generally applicable to the ownership and disposition of our Ordinary Shares by a U.S. holder (as defined below) that acquires our Ordinary Shares and holds our Ordinary Shares as "capital assets" (generally, property held for investment) under the United States Internal Revenue Code of 1986, as amended (the "Code"). This discussion is based upon existing United States federal income tax law, which is subject to differing interpretations and may be changed, possibly with retroactive effect. No ruling has been sought from the Internal Revenue Service (the "IRS") with respect to any United States federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This discussion does not address all aspects of United States federal income taxation that may be important to particular investors in light of their individual circumstances, including investors subject to special tax rules (for example, certain financial institutions, insurance companies, broker-dealers, traders in securities that have elected the mark-to-market method of accounting for their securities, partnerships and their partners, regulated investment companies, real estate investment trusts, and tax-exempt organizations (including private foundations)), investors who are not U.S. holders, investors who own (directly, indirectly, or constructively) 10% or more of our stock (by vote or value), investors that will hold their Ordinary Shares as part of a straddle, hedge, conversion, constructive sale, or other integrated transaction for United States federal income tax purposes, investors required to accelerate the recognition of any item of gross income with respect to our Ordinary Shares as a result of such income being recognized on an applicable financial statement, or investors that have a functional currency other than the United States dollar, all of whom may be subject to tax rules that differ significantly from those summarized below. In addition, this discussion does not discuss any non-United States, alternative minimum tax, state, or local tax or any non-income tax (such as the U.S. federal gift or estate tax) considerations, or the Medicare tax on net investment income. Each U.S. holder is urged to consult its tax advisor regarding the United States federal, state, local, and non-United States income and other tax considerations of an investment in our Ordinary Shares.

General

For purposes of this discussion, a "U.S. holder" is a beneficial owner of our Ordinary Shares that is, for United States federal income tax purposes, (i) an individual who is a citizen or resident of the United States, (ii) a corporation (or other entity treated as a corporation for United States federal income tax purposes) created in, or organized under the laws of, the United States or any state thereof or the District of Columbia, (iii) an estate the income of which is subject to United States federal income taxation regardless of its source, or (iv) a trust (A) the administration of which is subject to the primary supervision of a United States court and which has one or more United States persons who have the authority to control all substantial decisions of the trust or (B) that has otherwise elected to be treated as a United States person under the Code or applicable United States Treasury regulations.

If a partnership (or other entity or arrangement treated as a partnership for United States federal income tax purposes) is a beneficial owner of our Ordinary Shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. Partnerships holding our Ordinary Shares and partners in such partnerships are urged to consult their tax advisors as to the particular United States federal income tax consequences of an investment in our Ordinary Shares.

Sale or Other Disposition of Ordinary Shares

Subject to the PFIC rules discussed below, a U.S. holder will generally recognize capital gain or loss upon the sale or other disposition of Ordinary Shares in an amount equal to the difference between the amount realized upon the disposition and the U.S. holder's adjusted tax basis in such Ordinary Shares. Any capital gain or loss will be long-term if our Ordinary Shares have been held for more than one year and will generally be United States source gain or loss for United States foreign tax credit purposes. Long-term capital gain of individuals and other non-corporate U.S. holders is generally eligible for a reduced rate of taxation. The deductibility of a capital loss may be subject to limitations.

In the event that we are treated as a PRC "resident enterprise" under the Enterprise Income Tax Law and gain from the disposition of our Ordinary Shares is subject to tax in the PRC, a U.S. holder that is eligible for the benefits of the income tax treaty between the United States and the PRC may elect to treat the gain as PRC source income. If a U.S. holder is not eligible for the benefits of the income tax treaty or fails to make the election to treat any gain as foreign source, then such U.S. holder may not be able to use the foreign tax credit arising from any PRC tax imposed on the disposition of our Ordinary Shares unless such credit can be applied (subject to applicable limitations) against U.S. federal income tax due on other income derived from foreign sources in the same income category (generally, the passive category). U.S. holders are advised to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on a disposition of our Ordinary Shares, including the availability of the foreign tax credit under their particular circumstances and the election to treat any gain as PRC source.

Passive Foreign Investment Company Rules

If we are a PFIC for any taxable year during which a U.S. holder holds our Ordinary Shares, and unless the U.S. holder makes a mark-to-market election (as described below), the U.S. holder will generally be subject to special tax rules that have a penalizing effect, regardless of whether we remain a PFIC, for subsequent taxable years, on (i) any excess distribution that we make to the U.S. holder (which generally means any distribution paid during a taxable year to a U.S. holder that is greater than 125% of the average annual distributions paid in the three preceding taxable years or, if shorter, the U.S. holder's holding period for our Ordinary Shares), and (ii) any gain realized on the sale or other disposition, including, under certain circumstances, a pledge, of Ordinary Shares. Under the PFIC rules:

- such excess distribution and/or gain will be allocated ratably over the U.S. holder's holding period for our Ordinary Shares;
- such amount allocated to the current taxable year and any taxable years in the U.S. holder's holding period prior to the first taxable year in which we are a PFIC, or pre-PFIC year, will be taxable as ordinary income;
- such amount allocated to each prior taxable year, other than a pre-PFIC year, will be subject to tax at the highest tax rate in effect for that year; and
- an interest charge generally applicable to underpayments of tax will be imposed on the tax attributable to each prior taxable year, other than a pre-PFIC year.

If we are a PFIC for any taxable year during which a U.S. holder holds our Ordinary Shares and any of our non-United States subsidiaries is also a PFIC, such U.S. holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules. U.S. holders are advised to consult their tax advisors regarding the application of the PFIC rules to any of our subsidiaries.

As an alternative to the foregoing rules, a U.S. holder of "marketable stock" in a PFIC may make a mark-to-market election with respect to our Ordinary Shares, provided that our Ordinary Shares are regularly traded on the Nasdaq Global Market.

Because a mark-to-market election cannot be made for any lower-tier PFICs that a PFIC may own, a U.S. holder who makes a mark-to-market election with respect to our Ordinary Shares will generally continue to be subject to the general PFIC rules with respect to such U.S. holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for United States federal income tax purposes. If a mark-to-market election is made, the U.S. holder will generally (i) include as ordinary income for each taxable year that we are a PFIC the excess, if any, of the fair market value of Ordinary Shares held at the end of the taxable year over the adjusted tax basis of such Ordinary Shares and (ii) deduct as an ordinary loss the excess, if any, of the adjusted tax basis of our Ordinary Shares over the fair market value of such Ordinary Shares held at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. The U.S. holder's adjusted tax basis in our Ordinary Shares would be adjusted to reflect any income or loss resulting from the mark-to-market election. If a U.S. holder makes an effective mark-to-market election, in each year that we are a PFIC any gain recognized upon the sale or other disposition of our Ordinary Shares will be treated as ordinary income and loss will be treated as ordinary loss, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. If a U.S. holder makes a mark-to-market election it will be effective for the taxable year for which the election is made and all subsequent taxable years unless our Ordinary Shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

If a U.S. holder makes a mark-to-market election in respect of a PFIC and such corporation ceases to be a PFIC, the U.S. holder will not be required to take into account the mark-to-market gain or loss described above during any period that such corporation is not a PFIC.

We do not intend to provide information necessary for U.S. holders to make qualified electing fund elections, which, if available, would result in tax treatment different from (and generally less adverse than) the general tax treatment for PFICs described above.

If a U.S. holder owns our Ordinary Shares during any taxable year that we are a PFIC, such holder would generally be required to file an annual IRS Form 8621. Each U.S. holder is advised to consult its tax advisors regarding the potential tax consequences to such holder if we are or become a PFIC, including the possibility of making a mark-to-market election.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We have filed this Annual Report on Form 20-F with the SEC under the Exchange Act. Statements made in this report as to the contents of any document referred to are not necessarily complete. With respect to each such document filed as an exhibit to this report, reference is made to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by such reference.

We are subject to the informational requirements of the Exchange Act as a foreign private issuer and file reports and other information with the SEC. Reports and other information filed by us with the SEC including this report, may be inspected and copied at the public reference room of the SEC at 100 F Street, N.E., Washington D.C. 20549. You can also obtain copies of this report by mail from the Public Reference Section of the SEC, 100 F. Street, N.E., Washington D.C. 20549, at prescribed rates. Additionally, copies of this material may be obtained from the SEC's Internet site at http://www.sec.gov. The SEC's telephone number is 1-800-SEC-0330. In accordance with Nasdaq Stock Market Rule 5250(d), we will also post this Annual Report on Form 20-F on our website at www.kbsfashion.com.

As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

I. Subsidiary Information

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

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Exchange Risk

Foreign currency risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. Substantially all of our revenue-generating transactions, and a majority of our expense-related transactions, are denominated in Renminbi, which is the functional currency of our operations. We do not hedge against currency risk.

The value of the Renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. To the extent that we need to convert U.S. dollars into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would reduce the Renminbi amount we receive from the conversion. Conversely, if we decide to convert Renminbi into U.S. dollars for the purpose of making payments for dividends on our Ordinary Shares, servicing outstanding debts, or for other business purposes, appreciation of the U.S. dollar against the Renminbi would reduce the U.S. dollar amounts available to us.

Our functional currency is the RMB, and our financial statements are presented in U.S. dollars. The RMB appreciated by 8.23% and 2.34% for the year ended December 31, 2022 and 2021, respectively. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future. The change in the value of the RMB relative to the U.S. dollar may affect our financial results reported in the U.S. dollar terms without giving effect to any underlying changes in our business or results of operations. Currently, our assets, liabilities, revenues and costs are denominated in RMB.

Interest Rate Risk

We are not currently exposed to interest rate risk. We do not own any interest-bearing instruments and our interest-bearing debt carries a fixed rate.

Market Price Risk

We are not currently exposed to commodity price risk or market price risk.

Inflation

Inflation does not materially affect our business or the results of our operations.

Seasonality

Seasonality does not materially affect our business or the results of our operations.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

As of the date of this Annual Report, we had the following warrants and options outstanding:

Our independent director, Wenzhang Jia, holds options to purchase 1,886 Ordinary Shares of the Company, exercisable at a price of $5.30 per share, which options vest in equal monthly installments over the course of Mr. Jia's initial year of service and are exercisable for a term of 10 years.

Our independent director, Huijuan Zhao, holds options to purchase 740 Ordinary Shares of the Company, exercisable at a price of $13.51 per share, which options vest in equal monthly installments over the course of Ms. Zhao's initial year of service and are exercisable for a term of 10 years.

Our former independent director, Heung Ming Wong, presently holds options to purchase 361 Ordinary Shares of the Company, at an exercise price of $8.90 per share. The options vested in equal monthly installments over Mr. Wong's initial year of service and are exercisable for a term of ten years. At the time of his resignation, on June 10, 2022, all unvested Ordinary Shares held by Mr. Wong were forfeited.

C. Other Securities

Not applicable.

D. American Depositary Shares

We do not have any American Depositary Shares.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

As of December 31, 2022, our management assessed the effectiveness of our internal control over financial reporting. In the course of auditing our consolidated financial statements for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting as of December 31, 2022. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified to date relate to a lack of accounting staff and resources with appropriate knowledge of generally accepted accounting principles in the United States ("U.S. GAAP") and SEC reporting and compliance requirements.

As a result of the above material weaknesses, management has concluded that our internal control over financial reporting was ineffective as of December 31, 2022.

In order to address and resolve the foregoing material weakness, we have begun to implement measures designed to improve our internal control over financial reporting to remediate this material weakness. We plan to take remedial measures including (i) hiring more qualified accounting personnel with relevant U.S. GAAP and SEC reporting experience and qualifications to strengthen the financial reporting function and to set up a financial and system control framework; (ii) implementing regular and continuous U.S. GAAP accounting and financial reporting training programs for our accounting and financial reporting personnel; and (iii) setting up an internal audit function as well as engaging an external consulting firm to assist us with assessment of Sarbanes-Oxley compliance requirements and improvement of overall internal control. Finally, we intend to use approximately $1,000,000 from the net proceeds of our recent IPO to improve the internal control system, including adopting ERP system (Enterprise Resource Planning Administration) and robot management.

B. Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2022. The assessment was based on criteria established in the framework Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was not effective as of December 31, 2022. Our management identified the material weakness(es) in our internal control over financial reporting as insufficient in-house personnel in our accounting department with sufficient knowledge of the U.S. GAAP and SEC reporting rules.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or because the degree of compliance with policies or procedures may deteriorate.

C. Attestation Report of the Registered Public Accounting Firm

Because the Company is a non-accelerated filer and an emerging growth company, this Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC where domestic and foreign registrants that are non-accelerated filers, which we are, and "emerging growth companies," which we also are, are not required to provide the auditor attestation report.

D. Changes in Internal Controls over Financial Reporting

Other than as described above, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The audit committee of our board of directors currently consists of three members, Wenzhang Jia, Xiaoming E and Huijuan Zhao. Our board of directors has determined that all of our audit committee members are "independent" under the Exchange Act and have the requisite financial knowledge and experience to serve as members of our audit committee. In addition, our board of directors has determined that Wenzhang Jia is an "audit committee financial expert" as defined in Item 16A of the Instructions to Form 20-F and meets Nasdaq's financial sophistication requirements due to his current and past experience in various companies in which he was responsible for, amongst others, the financial oversight responsibilities.

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Business Conduct and Ethics (the "Code of Ethics") that applies to all of the directors, officers and employees of the Company and its subsidiaries, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Ethics addresses, among other things, honesty and ethical conduct, conflicts of interest, compliance with laws, regulations and policies, including disclosure requirements under the federal securities laws, confidentiality, trading on inside information, and reporting of violations of the code. A copy of the Code of Ethics is filed as Exhibit 14.1 to our amended registration statement on Form F-1 filed on August 10, 2021. During the fiscal year ended December 31, 2022, there were no waivers of our Code of Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees by categories specified below in connection with services rendered by our principal external auditors for the periods indicated.

	Fiscal Year Ended December 31,	
	2022	**2021**
Audit Fees*	$ 522,272	$ 220,000

* "Audit Fees" consisted of the aggregate fees billed for professional services rendered for the audit of our annual financial statements or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements.

Our Audit Committee pre-approves all auditing services and permitted non-audit services to be performed for us by our independent auditor, including the fees and terms thereof (subject to the de minimums exceptions for non-audit services described in Section 10A(i)(l)(B) of the Exchange Act that are approved by our Audit Committee prior to the completion of the audit).

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

There were no purchases of equity securities made by or on behalf of us or any "affiliated purchaser" as defined in Rule 10b-18 of the Exchange Act during the period covered by this Annual Report.

ITEM 16F. CHANGES IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

ITEM 16G. CORPORATE GOVERNANCE

We were incorporated in the Cayman Islands and our corporate governance practices are governed by applicable Cayman Islands law and our Memorandum and Articles. In addition, because our common stock is listed on Nasdaq, we are subject to Nasdaq's corporate governance requirements.

As a Cayman Islands company listed on the Nasdaq Global Market, we are subject to the Nasdaq corporate governance listing standards. Nasdaq rules, however, permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards.

Nasdaq Listing Rule 5605(b)(1) requires listed companies to have, among other things, a majority of its board members be independent. As a foreign private issuer, however, we are permitted to, and we may follow home country practice in lieu of the above requirements. The corporate governance practice in our home country, the Cayman Islands, does not require a majority of our board to consist of independent directors. Currently, a majority of our board members are independent. However, if we change our board composition such that independent directors do not constitute a majority of our board of directors, our shareholders may be afforded less protection than they would otherwise enjoy under Nasdaq's corporate governance requirements applicable to U.S. domestic issuers.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The financial statements are filed as part of this Annual Report beginning on page F-1.

ITEM 19. EXHIBITS

Exhibit Number	Description
1.1	Certificate of Incorporation of Meihua International Medical Technologies Co., Ltd., dated November 10, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
1.2	Amended and Restated Articles of Association of Meihua International Medical Technologies Co., Ltd., dated December 21, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
1.3	Amended and Restated Memorandum of Association of Meihua International Medical Technologies Co., Ltd., dated December 21, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
2.1	Registrant's Specimen Certificate for Ordinary Shares (Incorporated by reference to Registration Statement on Form F-1 /A filed September 13, 2021)
2.2	Description of Securities***
4.1	Share Exchange Agreement by and among Meihua International Medical Technologies Co., Ltd., Kang Fu International Medical Co., Limited, and shareholders of Kang Fu International Medical Co., Limited, dated December 21, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.2	English Translation of Employment Agreement between Meihua International Medical Technologies Co., Ltd. and its CEO Yulin Wang (Incorporated by reference to Registration Statement on Form F-1 /A filed September 13, 2021)
4.3	English Translation of Form of Sales Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd. and our customer (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.4	English Translation of Form of Purchase Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd. and our supplier (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.5	English Translation of Form of Distributor Purchase Agreement between Jiangsu Yada Technology Group Co., Ltd and our distributor (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.6	English Translation of Loan Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd as borrower, and Bank of Communications Limited Yangzhou Branch as lender, dated August 24, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.7	English Translation of Loan Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd and Yongjun Liu as borrowers and Agricultural Bank of China Yangzhou Runyang Branch as lender, and Mortgage Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd as mortgagor and Agricultural Bank of China Yangzhou Runyang Branch as mortgagee, dated December 3, 2019 (Incorporate$`by reference to Regis4ration Statement on Form F-1 filed August 10, 2021)
4.8	English Translation of Lease Agreement between Zhu Yi and Yangzhou Huada Medical Device Co., Ltd, dated November 20, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.9	English Translation of Lease Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd and Yangzhou Huada Medical Device Co., Ltd, dated December 7, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.10	English Translation of Lease Agreement between Yangzhou Huada Medical Device Co., Ltd and Jiangsu Huadong Medical Device Industrial Con Ltd, dated December 7, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.11	English Translation of Lease Agreement between Jiangsu Huadong Medical Device Industrial Co., Ltd and Jiangsu Yada Technology Group Co., Ltd, dated December 7, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.12	English Translation of Lease Agreement between Jiangsu Yada Technology Group Co., Ltd and Yangzhou Huada Medical Device Co., Ltd, dated December 7, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.13	English Translation of Lease Agreement between Jiangsu Yada Technology Group Co., Ltd and Jiangsu Huadong Medical Device Industrial Co., Ltd, dated December 7, 2020 (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.14	English Translation of Agreement of Persons Acting-in-concert (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
4.15	Collaboration Agreement with Zhong Jiang (Incorporated by reference to Registration Statement on Form F-1/A filed August 31, 2021)
4.16	Form of Indemnification Escrow Agreement 0(Incorporated by reference to Registration Statement on Form F-1/A filed December 2, 2021)
4.17	Form of Lock-up Agreement (included as Exhibit A to Underwriting Agreement) (Incorporated by reference to Registration Statement on Form F-1/A filed December 2, 2021)

4.18	Director Service Agreement with Heung Ming Wong (Incorporated by reference to Current Report on Form 6-K filed February 24, 2022)
4.19	Director Service Agreement with Xiaoming E (Incorporated by reference to Current Report on Form 6-K filed February 24, 2022)
4.20	Director Service Agreement with Xu Han (Incorporated by reference to Current Report on Form 6-K filed February 24, 2022)
4.21	Form of Director Service Agreement with Wenzhang Jia (Incorporated by reference to Current Report on Form 6-K filed June 28, 2022)
4.22	Form of Indemnification Agreement with the Meihua International Medical Technologies Co., Ltd. directors and officers (Incorporated by reference to Current Report on Form 6-K filed February 28, 2023)
4.23	Employment Agreement, effective December 1, 2022, between Meihua International Medical Technologies Co., Ltd. and Xin Wang. (Incorporated by reference to Exhibit 10.1 of Current Report on Form 6-K filed December 5, 2022)
4.24	Employment Agreement, effective December 1, 2022, between Meihua International Medical Technologies Co., Ltd. and Lianzhang Zhao. (Incorporated by reference to Exhibit 10.2 of Current Report on Form 6-K filed December 5, 2022)
4.25	Director Offer Letter, effective December 1, 2022, between Meihua International Medical Technologies Co., Ltd. and Huijuan Zhao. (Incorporated by reference to Exhibit 10.3 of Current Report on Form 6-K filed December 5, 2022)
4.26	Form of Indemnification Agreement with Registrant's Directors and Officers (Incorporated by reference to Exhibit 99.1 of Current Report on Form 6-K filed February 28, 2023)
8.1	List of Subsidiaries (Incorporated by reference to Exhibit 8.1 of Annual Report on Form 20-F filed July 29, 2022)
11.1	Code of Business Conduct and Ethics of the Registrant (Incorporated by reference to Registration Statement on Form F-1 filed August 10, 2021)
12.1	Certifications of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-1(a)(3)*
12.2	Certifications of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-1(a)(3)*
13.1	Certifications of Chief Executive Officer Pursuant to Rule 13a-14(b) (17 CFR 240.13a-14(b)) or Rule 15d-14(b) (17 CFR 240.15d-14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).**
13.2	Certifications of Chief Financial Officer Pursuant to Rule 13a-14(b) (17 CFR 240.13a-14(b)) or Rule 15d-14(b) (17 CFR 240.15d-14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).**
99.1	Earnings Press Release, dated April 14, 2023***
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)*

* Filed with this amended annual report on Form 20-F
** Furnished with this amended annual report on Form 20-F
*** Previously filed in the original annual report on Form 20-F.

SIGNATURE

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this report on its behalf.

Date: August 29, 2023

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES LIMITED

/s/ Xin Wang

Xin Wang
Chief Executive Officer

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES CO., LTD.
CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEARS ENDED

DECEMBER 31, 2022 AND 2021

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Meihua International Medical Technologies Co., Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Meihua International Medical Technologies Co., Ltd. (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of income and comprehensive income, changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, and the related notes to the financial statements (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on the entity's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Kreit & Chiu CPA LLP
(Formerly Paris, Kreit & Chiu CPA LLP)

We have served as the Company's auditor since 2022.

New York, New York
April 14, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Meihua International Medical Technologies Co., Ltd

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Meihua International Medical Technologies Co., Ltd and subsidiaries (collectively, the "Company") as of December 31, 2020, and the related consolidated statements of income and comprehensive income, changes in shareholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Briggs & Veselka Co.

Houston, Texas
June 4, 2021

We have served as the Company's auditor since 2021.

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES CO., LTD.
CONSOLIDATED BALANCE SHEETS
As of December 31, 2022 and 2021
(US$, except share data or otherwise noted)

	2022	2021
Assets		
Current Assets		
Cash	$ 26,736,700	$ 8,149,276
Bank acceptance receivables	22,085,846	19,379,845
Accounts receivable	68,945,792	67,101,297
Inventories	1,122,038	1,251,393
Prepayment and other current assets	16,428,779	1,394,539
Total current assets	135,319,155	97,276,350
Property, plant and equipment	8,758,047	7,477,744
Intangible assets	497,600	562,001
Investment	6,669,655	941,531
Other noncurrent assets	12,333,122	-
Deposits	-	30,599,755
Total assets	$ 163,577,579	$ 136,857,381
Liabilities and shareholders' equity		
Liabilities		
Current liabilities		
Short-term bank borrowings	$ 6,089,428	$ 5,178,420
Accounts payable	16,096,165	20,981,041
Taxes payable	1,131,276	2,082,252
Accrued expenses and other current liabilities	856,698	847,066
Total current liabilities	24,173,567	29,088,779
Long term loan	724,932	-
Total liabilities	24,898,499	29,088,779
Commitments and contingencies		
Shareholders' equity		
Ordinary share, $0.0005 par value, 80,000,000 shares authorized, 23,940,000 and 20,000,000 shares issued and outstanding as of December 31, 2022 and 2021, respectively	11,970	10,000
Preferred share, $0.0005 par value, 20,000,000 shares authorized, no shares issued and outstanding as of December 31, 2022 and 2021	-	-
Additional paid-in capital	42,967,006	9,716,484
Statutory surplus reserves	15,665,860	15,178,467
Retained earnings	83,330,239	77,574,663
Accumulated other comprehensive income (loss)	(3,852,138)	5,288,988
Total shareholders' equity	138,122,937	107,768,602
Non-controlling interest	556,143	-
TOTAL EQUITY	138,679,080	107,768,602
Total liabilities and shareholders' equity	$ 163,577,579	$ 136,857,381

The accompanying notes form an integral part of these consolidated financial statements.

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES CO., LTD.
CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME
For the years ended December 31, 2022, 2021 and 2020
(US$, except share data or otherwise noted)

	For the Years Ended December 31,		
	2022	**2021**	**2020**
Revenues			
Third party sales	$ 103,317,145	$ 103,461,809	$ 88,244,403
Related party sales	29,196	575,901	816,607
Total revenues	103,346,341	104,037,710	89,061,010
Cost of revenues	65,247,864	64,232,469	51,900,823
Gross profit	38,098,477	39,805,241	37,160,187
Operating expenses			
Selling	7,109,524	6,457,801	6,624,332
General and administrative	12,468,551	4,361,472	4,577,570
Research and development	2,962,904	2,725,014	2,492,059
Written-off Tai He deposit	4,755,536	-	-
Total operating expenses	27,296,515	13,544,287	13,693,961
Income from operations	10,801,962	26,260,954	23,466,226
Other (income) expense:			
Interest expense	194,667	180,744	137,160
Interest income	(63,725)	(23,855)	(36,583)
Currency exchange gain	(273,432)	(174,413)	(393,478)
Other expense, net	53,205	50,437	25,551
Total other (income) expenses	(89,285)	32,913	(267,350)
Income before income tax provision	10,891,247	26,228,041	23,733,576
Income taxes expense	4,713,543	5,278,462	4,688,321
Net income	6,177,704	$ 20,949,579	$ 19,045,255
Net loss attributable to non-controlling interests	(65,265)	-	-
Net income attributable to shareholders	6,242,969	20,949,579	19,045,255
Foreign currency translation adjustment – gain / (loss)	(9,155,028)	2,083,243	4,759,973
Comprehensive (loss) income	$ (2,977,324)	$ 23,032,822	$ 23,805,228
Comprehensive loss attributable to non-controlling interests	(79,167)	-	-
Comprehensive (loss) income attributable to shareholders	(2,898,157)	23,032,822	23,805,228
Weighted average number of ordinary shares - basic and diluted	23,411,068	20,000,000	20,000,000
Basic & diluted net income per ordinary share	$ 0.27	$ 1.05	$ 0.95

The accompanying notes form an integral part of these consolidated financial statements.

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES CO., LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
For the years ended December 31, 2022, 2021 and 2020
(US$, except share data)

	Ordinary shares	Ordinary shares amount	Additional paid-in capital	Ordinary shares subscribed	Statutory surplus reserves	Retained earnings	Accumulated other comprehensive income (loss)	Non-controlling interests	Total Equity
Balance as of December 31, 2019	18,575,000	$ 9,288	$ 8,100,225	$ 344,739	$ 13,308,334	$ 39,449,962	$ (1,554,228)	-	$ 59,658,320
Share issuance	1,425,000	712	1,616,259	-	-	-	-	-	1,616,971
Ordinary shares subscribed	-	-	-	(344,739)	-	-	-	-	(344,739)
Net income	-	-	-	-	-	19,045,255	-	-	19,045,255
Appropriation of statutory reserve	-	-	-	-	1,870,133	(1,870,133)	-	-	-
Currency translation adjustment	-	-	-	-	-	-	4,759,973	-	4,759,973
Balance as of December 31, 2020	20,000,000	$ 10,000	$ 9,716,484	-	$ 15,178,467	$ 56,625,084	$ 3,205,745	-	$ 84,735,780
Net income	-	-	-	-	-	20,949,579	-	-	20,949,579
Currency translation adjustment	-	-	-	-	-	-	2,083,243	-	2,083,243
Balance as of December 31, 2021	20,000,000	$ 10,000	$ 9,716,484	-	$ 15,178,467	$ 77,574,663	$ 5,288,988	-	$ 107,768,602
Ordinary shares subscribed	3,940,000	1,970	33,250,522	-	-	-	-	-	33,252,492
Shareholders' contribution	-	-	-	-	-	-	-	635,310	635,310
Net income	-	-	-	-	-	6,242,969		(65,265)	6,177,704
Appropriation of statutory reserve	-	-	-	-	487,393	(487,393)			
Currency translation adjustment	-	-	-	-	-		(9,141,126)	(13,902)	(9,155,028)
Balance as of December 31, 2022	23,940,000	11,970	42,967,006	-	15,665,860	83,330,239	(3,852,138)	556,143	138,679,080

The accompanying notes form an integral part of these consolidated financial statements.

MEIHUA INTERNATIONAL MEDICAL TECHNOLOGIES CO., LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2022, 2021 and 2020
(US$)

	For the Year Ended December 31		
	2022	**2021**	**2020**
Cash Flows from operating activities:			
Net income	$ 6,177,704	$ 20,949,579	$ 19,045,255
Adjustments for items not affecting cash:			
Depreciation	541,265	595,522	497,238
Amortization	22,196	26,951	26,195
Net loss from disposal of property, plant and equipment	25,023	15,281	2,852
Written-off Tai He deposit	4,755,536	-	-
Currency exchange (gain) loss	(273,432)	-	-
Changes in operating assets and liabilities:			-
Bank acceptance receivables	(4,284,515)	(6,533,717)	(5,764,940)
Accounts receivable	(7,121,889)	(20,065,904)	(13,644,830)
Inventories	35,027	105,121	(219,787)
Prepayments and other assets	(4,932,145)	(861,799)	(367,249)
Due from related parties	-	396,583	(222,504)
Accounts payable	(3,371,275)	4,908,971	5,341,710
Taxes payable	(812,412)	288,659	598,105
Accrued expenses and other current liabilities	75,879	120,090	102,749
Due to related parties	-	-	(68,798)
Net cash (used in) provided by operating activities	(9,163,038)	(54,663)	5,325,996
Cash flows from investing activities:			
Purchases of property, plant and equipment	(2,698,729)	(850,231)	(3,808,259)
Payments for long-term deposits for buildings	-	-	(12,311,347)
Long term investment	(5,944,709)	-	-
Proceeds from disposal of property, plant and equipment	23,146	16,414	25,202
Net cash used in investing activities	(8,620,292)	(833,817)	(16,094,404)
Cash flows from financing activities:			
Proceeds from short-term bank borrowings	7,579,135	6,510,820	4,359,665
Proceeds from long-term bank loans	743,052	-	-
Capital contributed by non-controlling shareholders	635,310	-	-
Proceeds from initial public offering	34,529,644	-	-
Proceeds from issuance of shares	0	-	1,272,232
Repayments of short-term bank borrowings	(6,241,641)	(4,650,586)	(3,925,147)
Net cash provided by financing activities	37,245,500	1,860,234	1,706,750
Effect of foreign exchange rate changes	(874,746)	(9,812)	218,137
Net increase (decrease) in cash	18,587,424	961,942	(8,843,521)
Cash, beginning of year	8,149,276	7,187,334	16,030,855
Cash, end of year	$ 26,736,700	$ 8,149,276	$ 7,187,334
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:			
Cash paid during the period for:			
Interest	$ 194,667	$ 180,744	$ 137,160
Income taxes	$ 5,703,288	$ 5,042,816	$ 4,362,169
Non-cash transactions			
Shareholder contribution through deferred cost	1,277,152		

The accompanying notes form an integral part of these consolidated financial statements.

1. Organization and principal activities

Principal Activities:

Meihua International Medical Technologies Co., Ltd. ("Meihua") was incorporated on November 10, 2020 in the Cayman Islands. It is a holding company with no operations. Meihua produces and sells medical consumables through its wholly owned subsidiaries located in People's Republic of China ("PRC" or "China"). Below is Meihua's organizational chart, as well as a description of the ownership structure.

Entity Name	Registered Location	Percentage of ownership	Date of incorporation	Principal activities
Meihua International Medical Technologies Co., Ltd. (“Meihua”)	Cayman	Parent	November 10, 2020	Investment holding
康复国际医疗有限公司 Kang Fu International Medical Co., Limited (“Kang Fu”)	Hong Kong	100% by Meihua	October 13, 2015	Investment holding
扬州华达医疗器械有限公司 Yangzhou Huada Medical Equipment Co., Ltd. (“Huada”)	Yangzhou	100% by Kang Fu	December 24, 2001	Medical Equipment Sales
江苏亚达科技集团有限公司 Jiangsu Yada Technology Group Co., Ltd. (“Yada”)	Yangzhou	100% by Huada	December 5, 1991	Medical Equipment Sales
江苏华东医疗器械实业有限公司 Jiangsu Huadong Medical Device Industry Co., Ltd. (“Huadong”)	Yangzhou	100% by Yada	November 18, 2000	Medical Equipment Sales
扬州光辉医疗科技有限公司 Yangzhou Guanghui Medical Technology Co., Ltd. (“Guanghui”)	Yangzhou	100% by Huadong	December 22, 2020	Medical Equipment Sales
海南国械医疗科技有限公司 Hainan GuoxieTechnology Group Co. Ltd. (“Hainan Guoxie”)	Hainan	55% by Kang Fu	October 07,2021	Medical Equipment Sales

Kang Fu was incorporated on October 13, 2015 with a registered capital of HKD 53,911,815 ($6,911,771). Kang Fu is a holding company with no operations. The following operating entities (Huada, Yada and Huadong) are all directly and indirectly 100% owned by Kang Fu for all the periods presented.

Huada is a subsidiary wholly owned by Kang Fu and established in Yangzhou, China on December 24, 2001 with a registered capital of $ 17,193,021.

Yada is a subsidiary wholly owned by Huada and was established in Yangzhou, China on December 5, 1991 with a registered capital of RMB51,390,000.

Huadong is a subsidiary wholly owned by Yada and was established in Yangzhou, China on November 18, 2000 with a registered capital of RMB50,000,000.

Those three subsidiaries primarily manufacture and sell Class I, II and III disposable medical devices under the Company’s own brands, and distribute Class I, II and III disposable medical devices sourced from other manufacturers to our domestic and overseas customers.

Guanghui is a subsidiary wholly owned by Huadong and was established in Yangzhou, China on December 22, 2020 with a registered capital of RMB1,000,000.

Hainan Guoxie is a subsidiary 55% owned by Kang Fu and established in Hainan, China on October 07, 2021 with a registered capital of RMB100,000,000.

Reorganization and Share Issuance

On November 10, 2020, Meihua was incorporated in the Cayman Islands and issued 50,000 ordinary shares at par value of $1.00 to Yongjun Liu.

On December 21, 2020, Yongjun Liu surrendered 49,999 shares to the Company for cancellation. The Company subdivided each existing share with a par value of $1.00 into 2,000 shares with a par value of $0.0005 par value and created a new class of preferred shares. Upon completion of the share capital changes, the Company's share capital includes 80,000,000 ordinary shares with a par value of $0.0005 per share and 20,000,000 preferred shares with a par value of $0.0005 per share.

Also on December 21, 2020, the Company engaged in a corporate reorganization to combine the controlled entities (now referred to as the subsidiaries) into one legal corporation (the Company). The specific transactions related to this reorganization are outlined below. The Company entered into a share exchange agreement with Kang Fu to issue an aggregate of 15,933,000 ordinary shares to Yongjun Liu and Yin Liu in exchange for 100% ownership of Kang Fu, and allotted 2,640,000 ordinary shares at $0.0005 par value to three BVI companies held by founders of the Company for no consideration. On December 22, 2020, Guanghui was incorporated for the purpose of foreign exchange registration under the laws of the People's Republic of China as there was no substantive business of Guanghui. The shares of Guanghui are owned by 13 natural persons (the "Guanghui Shareholders") and on May 10, 2021, all of the Guanghui Shareholders agreed to transfer all their shares held in Guanghui to Huadong (an indirect subsidiary of the Company) for no consideration. Through such transaction, Guanghui then became a wholly owned subsidiary of Huadong.

On December 18, 2020, Yongjun Liu and Yin Liu and other shareholders (collectively, the "Parties") executed an Acting-in-Concert Agreement. The major terms of this agreement are:

- The Parties shall inform and discuss with each other and reach a consensus before exercising voting rights in the Company's decision making.
- If no consensus could be reached by the Parties, the decision made by Yongjun Liu and Yin Liu (who are a couple) prevails.

As a result of the Acting-in-Concert agreement, Yongjun Liu and Yin Liu together have the ultimate control of the Company.

The Acting-in-Concert Agreement that establishes the common control between Meihua International and Kang Fu is treated as though it was effective for all periods presented as during the years presented in these financial statements, the control of the entities has never changed (always under the control of Yongjun Liu and Yin Liu who are a couple). Accordingly, the combination has been treated as a corporate restructuring (reorganization) of entities under common control and thus the current capital structure has been retroactively presented in prior periods as if such structure existed at that time and in accordance with ASC 805-50-45-5, the entities under common control are presented on a combined basis for all periods to which such entities were under common control. Since all of the subsidiaries were under common control for the entirety of the years ended December 31, 2020, the results of these subsidiaries are included in the financial statements for all periods.

After the restructuring, Meihua holds 100% ownership of Kang Fu and has 80,000,000 ordinary shares and 20,000,000 preferred shares authorized, 18,575,000 ordinary shares and nil preferred share issued and outstanding.

The discussion and presentation of financial statements herein assumes the completion of the restructuring, which is accounted for retroactively as if it occurred on January 1, 2020, and the equity has been restated to reflect the change as well.

On December 22, 2020, the Company issued a total of 1,425,000 ordinary shares to three BVI companies with total consideration of $1,616,971 in a private offering. The consideration was received by Huada due to Meihua not having been incorporated at the time of payments received. The timing of the payments received is listed below:

	US$
December 2019	344,739
January 2020	359,885
April 2020	508,814
September 2020	403,533
Total	1,616,971

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include all accounts of Meihua and its subsidiaries (collectively, the "Company") and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All inter-company transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported and disclosed in the consolidated financial statements and related notes.

The most significant estimates and judgments include allowance for bad debts, the valuation of inventory, useful life of property, plant and equipment and income taxes related to realization of deferred tax assets and uncertain tax position. Actual amounts could differ from those estimates.

Non-controlling interests

Non-controlling interest represents the portion of the net assets of subsidiaries attributable to interests that are not owned or controlled by the Company. The non-controlling interest is presented in the consolidated balance sheets, separately from equity attributable to the shareholders of the Company. Non-controlling interest's operating results are presented on the face of the consolidated statements of income and comprehensive income as an allocation of the total income for the year between non-controlling shareholders and the shareholders of the Company. As of December 31, 2022, non-controlling interests represent one non-controlling shareholders' proportionate share of equity interests in Hainan Guoxie.

Functional Currency and Foreign Currency Translation

The Company's reporting currency is the United States dollar ("US$"). The Company's operations are principally conducted through the PRC subsidiaries where the local currency is the functional currency. Therefore, the functional currency of Kang Fu is the Hong Kong dollar and the functional currency of Huada, Yada, Huadong and Guanghui is the Renminbi ("RMB").

Transactions denominated in currencies other than the functional currencies are translated into the functional currency of the entity at the exchange rates prevailing on the transaction dates. Monetary assets and liabilities denominated in currencies other than the applicable functional currency are translated into the functional currency at the prevailing rates of exchange at the balance date. The resulting exchange differences are reported in the consolidated statements of income and comprehensive income.

The assets and liabilities of the Company are translated at the exchange spot rate at the balance sheet date, stockholders' equity is translated at the historical rates and the revenues and expenses are translated at the average exchange rates for the periods. The resulting translation adjustments are reported under other comprehensive income in the consolidated statements of income and comprehensive income in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 220, *Comprehensive Income*. The following are the exchange rates that were used in translating the Company's PRC subsidiaries' financial statements into the consolidated financial statements:

	For the Years Ended December 31		
	2022	**2021**	**2020**
Period Ended spot	US$1=RMB 6.8972	US$1=RMB 6.3726	US$1=RMB 6.5250
Period Average	US$1=RMB 6.7290	US$1=RMB 6.4508	US$1=RMB 6.9042

The exchanges rates used for translation from Hong Kong dollar to US$ was 7.8000, a pegged rate determined by the linked exchange rate system in Hong Kong. This pegged rate was used to translate Kang Fu's balance sheets, income statement items and cash flow items for both the years ended December 31, 2022, 2021 and 2020.

Certain Risks and Concentration

The Company's financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and receivables. As of December 31, 2022 and 2021 substantially all the Company's cash were held in major financial institutions located in Hong Kong and the PRC, which management considers to be of high credit quality.

As of December 31, 2022, two customers accounted for approximately 27.63% and 10.97% of the Company's total revenues. As of December 31, 2021, two customers accounted for approximately 21.91% and 11.26% of the Company's total revenues.

As of December 31, 2022, two customers accounted for approximately 27.73% and 13.14% of the Company's accounts receivable. As of December 31, 2021, three customers accounted for approximately 25.88%, 11.41% and 10.25%, respectively, of the Company's accounts receivable.

For the year ended December 31, 2022, one supplier accounted for approximately 11.93% of the Company's total purchases There were no suppliers that individually represented greater than 10% of the total purchase of the Group for the years ended December 31, 2021 and 2020.

Fair Value Measurement

Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact, and it considers assumptions that market participants would use when pricing the asset or liability.

The Company adopted the guidance of Accounting Standards Codification ("ASC") 820 for fair value measurements which clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.

Level 2: Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.

Level 3: Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

The Company's financial instruments include cash, accounts receivable, bank acceptance receivables, due from related parties, accounts payable, other liabilities and accrued expenses and short-term bank borrowings. The carrying amounts approximate their fair values due to their short maturities as of December 31, 2022 and 2021.

The Company noted no transfers between levels during any of the periods presented. The Company did not have any instruments that were measured at fair value on a recurring or non-recurring basis as of December 31, 2022 and 2021.

Cash

Cash consists of petty cash on hand and cash held in banks, which are highly liquid and are unrestricted as to withdrawal or use.

Bank Acceptance Receivables

Bank acceptance receivables are issued by bank under the request of the Company's customers, to pay for the purchased goods. The Company can choose to hold acceptance notes until maturity and receive the face value payment from the bank, or sell (exchange) the acceptance notes at a discount to another party willing to wait until maturity to receive the bank's promised payment. The maturity date of the receivables is all within one year of the original issuance date and carried at face value. The Company is not lending money, it just sells goods to the customers (customers can pay the purchased goods by cash, accounts receivable or bank acceptance receivables). The receivables mature within one year, and are non-interest bearing. As bank acceptance receivables are issued by the banks and payments are guaranteed. The Company has not discounted any bank acceptances and there was no endorsed bank acceptances that are unmatured as of December 31, 2022. The Company collected approximately $9.6 million as of March 31, 2023.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable represent trade receivables and are recognized initially at fair value and subsequently adjusted for any allowance for doubtful accounts or impairment.

The Company records impairment losses for accounts receivable based on assessments of the recoverability of the trade and other receivables and individual account analysis, including the current creditworthiness and the past collection history of each debtor. Impairments arise when there is objective evidence indicating that the balances may not be collectible. The identification of bad and doubtful debts, in particular of a loss event, requires the use of judgment and estimates, which involve the estimates of specific losses on individual exposures, as well as a provision on historical trends of collections. Based on management of customers' credit and ongoing relationship, management makes conclusions whether any balances outstanding at the end of the period will be deemed non-collectible on an individual basis and on aging analysis basis. The provision is recorded against accounts receivables balances, with a corresponding charge recorded in the consolidated statements of operations and comprehensive income. Delinquent account balances are written-off against the allowance for doubtful accounts after management has determined that the likelihood of collection is not probable.

The Company historically has not had material bad debts in accounts receivable. There were no bad debt expenses related to accounts receivable for the years ended December 31, 2022, 2021 and 2020 and there was no provision for doubtful accounts as of December 31, 2022 and 2021.

Inventories

Inventories are valued using the lower of cost or net realizable value. Cost is principally determined using the weighted-average method. Manufactured inventories included cost of materials, labor and overhead expenses. The Company records adjustments to inventory for excess quantities, obsolescence, or impairment, when appropriate, to reflect inventory at net realizable value. These adjustments are based upon a combination of factors including current sales volume, market conditions, lower of cost or market analysis and expected realizable value of the inventory.

There were no write-downs recognized of inventories as of December 31, 2022 and 2021.

Prepayment and other current assets

As of December 31, 2022 and 2021, prepayment and other current assets were $16,428,779 and $1,394,539.

Prepayment and other assets primarily consist of deferred IPO costs, loans to third-parties, refundable tax credits and receivables, security deposits made to customers, advances to employees and land use right receivable, which are presented net of allowance for doubtful accounts. These balances are unsecured and are reviewed periodically to determine whether their carrying value has become impaired. The Company considers the balances to be impaired if the utilization or refund of the balances becomes doubtful. The Company uses the aging method to estimate the allowance for uncollectible balances. The allowance is also based on management's best estimate of specific losses on individual exposures, as well as a provision on historical trends of collections and utilizations. Actual amounts received or utilized may differ from management's estimate of credit worthiness and the economic environment. Delinquent account balances are written off against allowance for doubtful accounts after management has determined that the likelihood of collection is not probable. The allowance for doubtful accounts amounted to nil as of December 31, 2022 and 2021.

Deferred IPO costs represent the incremental costs incurred for the Company's initial public offering ("IPO"). These costs has been charged against the gross proceeds of the IPO in 2022 (see Note 14). Deferred IPO costs primary include specific legal, audit and professional consulting costs. As of December 31, 2022 and 2021, the deferred IPO costs were $nil and $1,277,152, respectively.

Property, Plant and Equipment

Property, plant and equipment items are recorded at their historic cost, less accumulated depreciation and impairment losses. The Company calculates depreciation using the straight-line method, after consideration of the estimated residual values, over the following estimated useful lives:

Category	Useful lives	Estimated residual value
Buildings	20 years	10%
Machinery and Equipment	10 years	10%
Motor vehicles	5 years	10%
Electronic Equipment	5 years	10%
Office Equipment	3 years	10%
Inspection Equipment	5 years	10%

Major improvements are capitalized and expenditures for maintenance and repairs are expensed as incurred. Construction in progress represents property, plant and equipment under construction or being installed. Costs include original cost, installation, construction and other direct costs. Interest expenses directly related to construction in progress would be capitalized. Construction in progress is transferred to the appropriate fixed asset account and depreciation commences when the asset has been substantially completed and placed in service.

Intangible Assets

Intangible assets are non-monetary assets without physical substance. These items are initially measured at cost and subsequently carried at cost less any accumulated amortization and impairment losses. Intangible assets with finite useful lives are amortized on a straight-line basis over their estimated useful lives. Amortization of finite-lived intangible assets is computed using the straight-line method over the estimated useful lives, which is as follows:

Category	Useful lives
Land use rights	50 years
Patent	5 years
Trademark	10 years

Impairment of Long-Lived Assets

The Company accounts for impairment of long-lived assets in accordance with Accounting Standards Codification ("ASC") 360, *Property, Plant and Equipment*. ("ASC 360"). Long-lived assets consist primarily of property, plant and equipment, and intangible assets. In accordance with ASC 360, the Company evaluates the carrying value of long-lived assets when it determines a triggering event has occurred, or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When indicators exist, recoverability of assets is measured by a comparison of the carrying value of the asset group to the estimated undiscounted future net cash flows expected to be generated by the asset. Examples of such triggering events include a significant disposal of a portion of such assets, and adverse change in the market involving the business employing the related assets. If such assets are determined not to be recoverable, the Company performs an analysis of the fair value of the asset group and will recognize an impairment loss when the fair value is less than the carrying amounts of such assets. The fair value, based on reasonable and supportable assumptions and projections, require subjective judgments. Depending on the assumptions and estimates used, the appraised fair value projected in the evaluation of long-lived assets can vary within a range of outcomes. The Company considers the likelihood of possible outcomes in determining the best estimate for the fair value of the assets. The Company did not record any impairment charges for the years ended December 31, 2022, 2021 and 2020. There can be no assurance that future events will not have impact on company revenue or financial position which could result in impairment in the future.

Investment

In accordance with Financial Accounting Standards Board ("FASB") ASC 321, "Investment-Equity Securities," the Company accounts for non-marketable securities on a prospective basis. Equity investments that do not have readily determinable fair values and do not qualify for the net asset value practical expedient are eligible for the measurement alternative.

On March 3, 2011, Yada invested in Yangzhou Juyuan Guarantee Co., Ltd ("Juyuan") and obtained 12% equity interest of Juyuan. For the Company's passive and without significant influence or control equity investment in private company which do not have readily determinable fair values, the Company has elected the measurement alternative defined as cost, less impairment, plus or minus adjustments resulting from observable price changes in orderly transactions for the identical or a similar investment of the Company. The investment is reviewed periodically to determine if its value has been impaired and adjustments are recorded as necessary in profit or loss for the period.

Investments in entities in which the Company can exercise significant influence but does not own a majority equity interest or control are accounted for using the equity method of accounting in accordance with ASC 323, Investments-Equity Method and Joint Ventures ("ASC 323"). Under the equity method, the Company initially records its investment at cost and the difference between the cost of the equity investee and the amount of the underlying equity in the net assets of the equity investee is accounted for as if the investee were a consolidated subsidiary. The share of earnings or losses of the investee are recognized in the consolidated statements of comprehensive loss. Equity method adjustments include the Company's proportionate share of investee income or loss, adjustments to recognize certain differences between the Company's carrying value and its equity in net assets of the investee at the date of investment, impairments, and other adjustments required by the equity method. The Company assesses its equity investment for other-than-temporary impairment by considering factors as well as all relevant and available information including, but not limited to, current economic and market conditions, the operating performance of the investees including current earnings trends, the general market conditions in the investee's industry or geographic area, factors related to the investee's ability to remain in business, such as the investee's liquidity, debt ratios, and cash burn rate and other company-specific information.

Investments in equity securities without readily determinable fair values are measured at cost minus impairment adjusted by observable price changes in orderly transactions for the identical or a similar investment of the same issuer. These investments are measured at fair value on a nonrecurring basis when there are events or changes in circumstances that may have a significant adverse effect. An impairment loss is recognized in the consolidated statements of comprehensive loss equal to the amount by which the carrying value exceeds the fair value of the investment. Prior to the adoption of ASU 2016-01 on January 1, 2019, these investments were accounted for using the cost method of accounting, measured at cost less other-than-temporary impairment.

On December 1, 2022, Huadong invested RMB 40 million into Jiangsu Zhongxiangxin International Science and Technology Innovation Park Co., Ltd. ("Zhongxiangxin"), and obtained 25% ownership interest of Zhongxiangxin. Zhongxiangxin manufactures and sells medical materials in the PRC. The Company accounted for the investments using equity method, because the Company has significant influence but does not own a majority equity interest or otherwise control over the equity investee. Under the equity method, the Company adjusts the carrying amount of the investment and recognizes investment income or loss for its share of the earnings or loss of the investee after the date of investment. When the Company's share of losses in the equity investee equals or exceeds its interest in the equity investee, the Company does not recognize further losses, unless the Company has incurred obligations or made payments or guarantees on behalf of the equity investee. For the year ended December 31, 2022, the investment gain from Zhongxiangxin was $290.

The Company continually reviews its investments in equity investees to determine whether a decline in fair value below the carrying value is other-than-temporary. The primary factors the Company considers in its determination include the financial condition, operating performance and the prospects of the equity investee; other company specific information such as recent financing rounds; the geographic region, market and industry in which the equity investee operates; and the length of time that the fair value of the investment is below its carrying value. If the decline in fair value is deemed to be other-than-temporary, the carrying value of the equity investee is written down to fair value.

For the years ended December 31, 2022, 2021 and 2020, no impairment indicators were identified and no loss related to revaluation of its investment in the private company was recorded.

Value-added Tax

Value-added taxes ("VAT") collected from customers relating to product sales and remitted to governmental authorities are presented on a net basis. VAT collected from customers is excluded from revenue which is recorded in VAT payable. The Company is subject to a VAT rate of 13%. The VAT payable may be offset by VAT paid by the Company on raw materials and other materials included in the cost of producing or acquiring its finished products.

Related Parties

Parties are considered to be related to the Company if the parties, directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with the Company. Related parties also include principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management and other parties with which the Company may deal with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests. The Company discloses all significant related party transactions.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC Topic 606 using the modified retrospective adoption method. Based on the requirements of ASC Topic 606, revenue is recognized when control of the promised goods or services is transferred to the customers in an amount that reflects the consideration the Company expects to be entitled to receive in exchange for those goods or services. The Company primarily sells its products to hospitals and medical equipment companies. Revenue is recognized when the following 5-step revenue recognition criteria are met:

1) Identify the contract with a customer

2) Identify the performance obligations in the contract

3) Determine the transaction price

4) Allocate the transaction price

5) Recognize revenue when or as the entity satisfies a performance obligation

Revenue from product sales is recognized at the point in time control of the products is transferred, generally upon customer receipt based upon the standard contract terms. Shipping and handling activities are considered to be fulfillment activities rather than promised services and are not, therefore, considered to be separate performance obligations. The Company's sales terms provide no right of return outside of a standard quality policy and returns are generally not significant. Payment terms for product sales are generally set at 90 to 180 days after the consideration becomes due and payable.

Revenue Disaggregation

The Company's disaggregated revenues are represented by two categories which are type of goods and type of customers.

Type of Goods

	For the year ended December 31,		
	2022	2021	2020
	US$	US$	US$
Self-Manufactured Products	50,514,976	48,059,165	44,473,076
Resales of Sourced Disposable Medical Devices from Third Party Manufacturers	52,831,365	55,978,545	44,587,934
Total Revenue	103,346,341	104,037,710	89,061,010

Type of Customers

	For the year ended December 31,		
	2022	2021	2020
	US$	US$	US$
Direct sales	9,465,644	9,499,748	9,430,082
Distributors	93,880,697	94,537,962	79,630,928
Total Revenue	103,346,341	104,037,710	89,061,010

Earnings per Ordinary Share

Earnings (loss) per ordinary share is calculated in accordance with ASC 260, *Earnings per Share*. Basic earnings (loss) per ordinary share is computed by dividing the net income (loss) attributable to shareholders of the Company by the weighted average number of ordinary shares outstanding during the year. Diluted earnings per ordinary share is computed in accordance with the treasury stock method and based on the weighted average number of ordinary shares and dilutive ordinary share equivalents. Dilutive ordinary share equivalents are excluded from the computation of diluted earnings per ordinary share if their effects would be anti-dilutive. There is no ordinary share equivalent issued to date.

Comprehensive Income (Loss)

ASC 220, Comprehensive Income ("ASC 220") establishes rules for reporting and display of comprehensive income and its components. ASC 220 requires that unrealized gains and losses on the Company's foreign currency translation adjustments be included in comprehensive income (loss).

Advertising Costs

The Company's advertising costs are expensed as incurred. Advertising expenses are included in selling expenses in the accompanying consolidated statements of income and comprehensive income. Advertising expenses were $95,432, $21,498 and $53,770 for the years ended December 31, 2022, 2021 and 2020, respectively.

Research and Development Costs

Research and development expenses are expensed as incurred. Research and development expenses were $2,962,904, $2,725,014 and $2,492,059 for the years ended December 31, 2022, 2021 and 2020, respectively.

Income Tax

Current income taxes are provided on the basis of net profit for financial reporting purposes, adjusted for income and expense items which are not assessable or deductible for income tax purposes, in accordance with the regulations of the relevant tax jurisdictions.

Deferred income taxes are recognized for temporary differences between the tax bases of assets and liabilities and their reported amounts in the consolidated financial statements, net operating loss carry forwards and credits. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Current income taxes are provided in accordance with the laws of the relevant taxing authorities. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in which temporary differences are expected to be reversed or settled. The effect on deferred tax assets and liabilities of changes in tax rates is recognized in the statement of comprehensive income in the period of the enactment of the change.

The Company considers positive and negative evidence when determining whether a portion or all of its deferred tax assets will more likely than not be realized. This assessment considers, among other matters, the nature, frequency and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, its experience with tax attributes expiring unused, and its tax planning strategies. The ultimate realization of deferred tax assets is dependent upon its ability to generate sufficient future taxable income within the carry-forward periods provided for in the tax law and during the periods in which the temporary differences become deductible. When assessing the realization of deferred tax assets, the Company has considered possible sources of taxable income including (i) future reversals of existing taxable temporary differences, (ii) future taxable income exclusive of reversing temporary differences and carryforwards, (iii) future taxable income arising from implementing tax planning strategies, and (iv) specific known trend of profits expected to be reflected within the industry.

The Company recognizes a tax benefit associated with an uncertain tax position when, in its judgment, it is more likely than not that the position will be sustained upon examination by a taxing authority. For a tax position that meets the more-likely-than-not recognition threshold, the Company initially and subsequently measures the tax benefit as the largest amount that the Company judges to have a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority. The Company's liability associated with unrecognized tax benefits is adjusted periodically due to changing circumstances, such as the progress of tax audits, case law developments and new or emerging legislation. Such adjustments are recognized entirely in the period in which they are identified. The Company's effective tax rate includes the net impact of changes in the liability for unrecognized tax benefits and subsequent adjustments as considered appropriate by management. The Company classifies interest and penalties recognized on the liability for unrecognized tax benefits as income tax expense.

Segment Reporting

FASB 280, "Segment Reporting," establishes standards for reporting information about operating segments on a basis consistent with the Company's internal organizational structure as well as information of the Company's business segments, geographical areas, segments and major customers. The Company uses the "management approach" in determining reportable operating segments. The management approach considers the internal organization and reporting used by the Company's chief operating decision maker for making operating decisions and assessing performance as the source for determining the Company's reportable segments. The chief operating decision maker is the Company's president and Chief Executive Officer ("CEO"). Management, including the chief operating decision maker, reviews operating results of different products at revenue level with no allocation of operating costs. Consequently, based on management's assessment, the Company has determined that it has only one operating segment as defined by FASB ASC 280.

The Company has disclosed the type of revenue by government category as follows.

	December 31, 2022			December 31, 2021			December 31, 2020		
		US$			US$			US$	
Category	Produced	Purchased	Total	Produced	Purchased	Total	Produced	Purchased	Total
Class I	7,463,707	8,572,512	16,036,219	6,151,443	7,331,962	13,483,405	5,181,532	6,155,223	11,336,755
Class II	37,229,199	36,177,490	73,406,689	36,788,116	41,313,745	78,101,861	35,863,806	33,573,351	69,437,157
Class III	1,189,906	1,863,990	3,053,896	1,094,957	2,291,899	3,386,856	758,525	2,355,768	3,114,293
Others	4,632,164	6,217,373	10,849,537	4,024,649	5,040,939	9,065,588	2,669,213	2,503,592	5,172,805
Total	50,514,976	52,831,365	103,346,341	48,059,165	55,978,545	104,037,710	44,473,076	44,587,934	89,061,010

Class I, II, and III medical devices are defined by the National Medical Products Administration of China according to their risk levels under the Regulation on the Supervision and Administration of Medical Devices (2021 Revision), Article 6 as follows:

- "Class I Medical Devices" means medical devices with low risks, whose safety and effectiveness can be ensured through routine administration.
- "Class II Medical Devices" means medical devices with moderate risks, which shall be strictly controlled and administered to ensure their safety and effectiveness.
- "Class III Medical Devices" means medical devices with relatively high risks, which shall be strictly controlled and administered through special measures to ensure their safety and effectiveness.

Furthermore, the Company has disclosed revenue by major product type included in each government category.

Category	Products	December 31, 2022 US$	December 31, 2021 US$	December 31, 2020 US$
Class I	Eye drops bottle	2,583,231	2,398,222	2,466,978
	Oral medicine bottle	3,965,345	3,263,135	2,200,569
	Anal bag	837,328	739,376	554,859
	Other Class I	8,650,315	7,082,672	6,114,349
Subtotal-Class I		16,036,219	13,483,405	11,336,755
Class II	Masks	410,163	600,534	9,632,150
	Identification tape	12,262,269	15,049,686	11,617,668
	Disposable medical brush	8,337,650	8,493,760	6,353,649
	Gynecological inspection kits	7,571,089	8,752,617	4,924,689
	Surgical kit	4,830,930	4,754,769	3,383,215
	Medical brush	5,231,299	4,130,703	3,635,190
	Medical kit	4,066,663	5,037,054	3,429,371
	Other Class II	30,696,626	31,282,738	26,461,225
Subtotal-Class II		73,406,689	78,101,861	69,437,157
Class III	Electronic pump	142,828	246,819	292,211
	Anesthesia puncture kit	539,615	430,288	438,047
	Disposable infusion pump	280,081	278,734	335,632
	Infusion pump	367,652	309,746	196,686
	Electronic infusion pump	44,812	291,725	185,030
	Laparoscopic trocar	139,284	219,901	134,585
	Other Class III	1,539,624	1,609,643	1,532,102
Subtotal-Class III		3,053,896	3,386,856	3,114,293
Others		10,849,537	9,065,588	5,172,805
Total		103,346,341	104,037,710	89,061,010

For the years ended December 31, 2022, 2021 and 2020, revenues and assets within PRC contributed over 99.5% of the Company's total revenues and assets.

The Outbreak of COVID-19

On January 30, 2020, the World Health Organization declared the outbreak of the coronavirus disease (COVID-19) a "Public Health Emergency of International Concern," and on March 11, 2020, the World Health Organization characterized the outbreak as a "pandemic." COVID-19 has had a severe and negative impact on the Chinese and the global economy and such impact persists as of the date of this annual report.

In fiscal year 2020, COVID-19 had a significant impact on our business and results of operations as the sales volume of masks rose sharply while the sales of products other than masks declined due to an overall decrease in market demand. In fiscal year 2021, with the stable control of the domestic epidemic in China, the market of masks was no longer in urgent shortage compared to the same period in 2020, and the production of epidemic prevention products resumed more normal production levels. In general, with the precise control of the epidemic in China, our production and operations have recovered smoothly, and the demand for other products has increased gradually. After the initial outbreak of COVID-19, from time to time, some instances of COVID-19 infections have emerged in various regions of China, including the infections caused by the Omicron variants in 2022. For example, a wave of infections caused by the Omicron variants emerged in Shanghai in 2022, and a series of restrictions and quarantines were implemented to contain the spread.

Many of the restrictive measures previously adopted by the PRC governments at various levels to control the spread of the COVID-19 virus have been revoked or replaced with more flexible measures since December 2022. While the revocation or replacement of the restrictive measures to contain the COVID-19 pandemic could have a positive impact on our normal operations, the extent of the impact on the Company's future financial results will be dependent on future developments such as the length and severity of the crisis, the potential resurgence of the crisis, future government actions in response to the crisis and the overall impact of the COVID-19 pandemic on the global economy and capital markets, among many other factors, all of which remain highly uncertain and unpredictable. Given this uncertainty, the Company is currently unable to quantify the expected impact of the COVID-19 pandemic on its future operations, financial condition, liquidity and results of operations if the current situation continues.

Recently adopted Accounting Standards

Effective January 1, 2020, the Company adopted ASU 2016-13, Financial Instruments – Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The new standard replaces the 'incurred loss methodology' credit impairment model with a new forward-looking "methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates." In applying the new standard, the Company has adopted the loss rate methodology to estimate historical losses on accounts receivables. The Company has adopted the aging methodology to estimate the credit losses on accounts receivables. The historical data is adjusted to account for forecasted changes in the macroeconomic environment in order to calculate the current expected credit loss. The Company's adoption of ASC 326 did not result in a material change in the carrying values of the Company's financial assets on the transition date.

In February 2016, FASB issued ASU No. 2016–02, Leases (Topic 842), ASC 842, and subsequently amended the guidance relating largely to transition considerations under the standard in July 2018. The new guidance, which creates new accounting and reporting guidelines for leasing arrangements, requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. The guidance also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The new standard is effective for public business entities for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early application permitted. In March 2019, the FASB issued ASU 2019-01, Leases (Topic 842) Codification Improvements, which further clarifies the determination of fair value of the underlying asset by lessors that are not manufacturers or dealers and modifies transition disclosure requirements for changes in accounting principles and other technical updates. The amendments in ASU 2019-01 amend Topic 842 and the effective date of those amendments is for fiscal years beginning December 15, 2019, and interim periods within those fiscal years for public business entities. For all other entities, ASC 842 is effective for annual periods beginning after December 15, 2021. For the year ended December 31, 2022, the Company only had an operating lease of office space from January 1, 2022 to December 31, 2022, and the Company did not have any finance lease. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes, which removes specific exceptions to the general principles in Topic 740 and to simplifies accounting for income taxes. The guidance is effective for public business entities for fiscal years beginning after December 15, 2020 and for interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In January 2020, the FASB issued ASU 2020-01, Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions between Topic 321, Topic 323, and Topic 815, which clarifies the interaction of the accounting for equity investments under Topic 321 and investments accounted for under the equity method of accounting in Topic 323 and the accounting for certain forward contracts and purchased options accounted for under Topic 815. The guidance is effective for public business entities for fiscal years beginning after December 15, 2021 and for interim periods within those fiscal years. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

In October 2021, the FASB issued ASU No. 2021-08, "'Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers" ("ASU 2021-08"). This ASU requires entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination. The amendments improve comparability after the business combination by providing consistent recognition and measurement guidance for revenue contracts with customers acquired in a business combination and revenue contracts with customers not acquired in a business combination. The amendments are effective for the Company beginning after December 15, 2023, and are applied prospectively to business combinations that occur after the effective date. The Company does not expect the adoption of ASU 2021-04 will have a material effect on the consolidated financial statements.

3. Prepayments and other assets

Prepayments and other current assets consist of the following:

	December 31, 2022	December 31, 2021
	US$	US$
Other receivable	239,148	117,389
Prepaid tax	250,410	-
Prepaid for land use right (1)	15,948,501	-
Prepaid for property (2)	12,323,842	-
Deferred IPO cost	-	1,277,150
Total	28,761,901	1,394,539
Less: non-current portion	12,333,122	-
Prepayments and other current assets	16,428,779	1,394,539

(1) On October 22, 2018, the Company signed a land use right agreement with the government of Touqiao Town, Yangzhou City and paid RMB 50 million ($7.25 million) and RMB 60 million ($8.70 million), respectively, in 2018 and 2019 according to the agreement. As a result of COVID-19, the land use right had not been transferred to the Company as scheduled. Both parties agreed to cancel the transaction and the funds that were prepaid for land use right will be returned to the Company before December 31, 2023. The balance was reclassified from deposits to prepayments and other current assets. (see Note 8)

(2) On April 20, 2020, the Company signed a factory building purchase agreement with Jiangsu Qionghua Group Co., Ltd. and paid deposit of RMB 85 million ($12.32 million). As a result of COVID-19, the factory building had not been completed as scheduled. Both parties agreed to cancel the transaction and that the deposit for the building would be returned to the Company on or before December 31, 2025, with such deposit accumulating interest at an annual interest rate of 3.5%. The balance was reclassified from deposits to prepayments and other current assets. (see Note 8)

4. Inventories

Inventories consist of the following:

	December 31, 2022	December 31, 2021
	US$	US$
Raw material	177,474	305,408
Work-in-process	343,795	224,694
Finished goods	560,119	682,699
Low-value consumables	40,650	38,592
Total	1,122,038	1,251,393

For the years ended December 31, 2022, 2021 and 2020, there were no writes-down of inventories.

5. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	December 31, 2022	December 31, 2021
	US$	US$
Buildings	7,343,492	9,552,700
Machinery and equipment	2,732,336	2,897,846
Motor vehicles	678,112	574,006
Electronic equipment	238,856	239,005
Office equipment	43,413	46,987
Inspection equipment	104,993	94,683
Construction in progress	1,394,146	657,880
Total	12,535,348	14,063,107
Less: accumulated depreciation	3,777,301	6,585,363
Property and equipment, net	8,758,047	7,477,744

Depreciation expense was $541,265, $595,522 and $497,238 for the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022 and 2021, the Company pledged buildings to secure bank borrowings to the Company as disclosed in Note 8.

6. Intangible Assets

Intangible assets consisted of the following:

	December 31, 2022	December 31, 2021
	US$	US$
Land use rights	752,887	814,865
Patents	28,997	31,384
Software	9,424	10,201
Trademarks	121,789	131,814
Total	913,097	988,264
Less: accumulated amortization	415,497	426,263
Intangible assets, net	497,600	562,001

Amortization expense was $22,196, $26,951 and $26,195 for the years ended December 31, 2022, 2021 and 2020, respectively.

The following table sets forth the Company's amortization expenses for the twelve months ending December 31 of the following years:

2023	$ 15,058
2024	15,058
2025	15,058
2026	15,058
2027	15,058
Thereafter	422,310
	$ 497,600

As of December 31, 2022 and 2021, the Company pledged land use rights to secure bank borrowings to the Company as disclosed in Note 8.

7. Investment

On March 3, 2011, Yada invested RMB 6 million into Yangzhou Juyuan Guarantee Co., Ltd. ("Juyuan") and obtained 12% equity interest of Juyuan. Juyuan mainly provides financing guarantee services and relevant consulting services to customers. Juyuan has only one executive director and one supervisor. Neither the executive director nor supervisor is related to Yada. Therefore, Yada has neither control nor significant influence over Juyuan. For the Company's passive and without significant influence or control equity investment in a private company which does not have readily determinable fair values, the Company has elected the measurement alternative defined as cost, less impairment, plus or minus adjustments resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

On December 1, 2022, Huadong invested RMB 40 million into Zhongxiangxin, and obtained 25% ownership interest of Zhongxiangxin. Zhongxiangxin manufactures and sells medical materials in the PRC. The Company accounted for the investments using the equity method, because the Company has significant influence but does not own a majority equity interest or otherwise control over the equity investee. Under the equity method, the Company adjusts the carrying amount of the investment and recognizes investment income or loss for its share of the earnings or loss of the investee after the date of investment. When the Company's share of losses in the equity investee equals or exceeds its interest in the equity investee, the Company does not recognize further losses, unless the Company has incurred obligations or made payments or guarantees on behalf of the equity investee. For the year ended December 31, 2022, the investment gain from Zhongxiangxin was $290.

For the years ended December 31, 2022, 2021 and 2020, no impairment indicators were identified and no loss related to revaluation of its investment in the private company was recorded.

8. Deposits

	December 31, 2022	December 31, 2021
	US$	US$
Deposits for land use right	-	17,261,400
Deposits for buildings	-	13,338,355
Total	-	30,599,755

On October 22, 2018, the Company signed a land use right agreement with the government of Touqiao Town, Yangzhou City and paid RMB 50 million ($7.85 million) and RMB 60 million ($9.42 million), respectively, in 2018 and 2019 according to the agreement. This contract is terminated and the payment is to be recovered. The balance was reclassified to prepayments and other current assets. (see Note 3)

On April 20, 2020, the Company signed a factory building purchase agreement with Jiangsu Qionghua Group Co., Ltd. and paid deposit of RMB 85 million ($13.34 million). This contract is terminated and the payment is to be recovered. The balance was reclassified to prepayments and other noncurrent assets. (see Note 3)

During the IPO, the Company entered into a series of agreements with Tai He International Group Limited ("Tai He"), a Hong Kong investment company. Pursuant to the agreements, Tai He agreed to invest a minimum of $35 million in the IPO subject to the Company making a $7.0 million refundable deposit and advancing a $3.0 million service fee for investor relations and other services payable to Tai He. The Company paid approximately $4.8 million to Tai He in 2022. The Company's affiliates and individual shareholders paid the rest of the agreed amount. Later the Company learned that Tai He did not invest in the IPO or provide any service to the Company. The Company is now proactively working to terminate the Tai He Agreements and recover the amount paid to Tai He by the Company. Due to the uncertainty of collection, the Company has written off the approximately $4.8 million deposit and fully expensed the $2.3 million service fee paid by the Company to Tai He in the year ended December 31, 2022.

9. Bank Borrowings

Bank borrowings are working capital loans from banks in China. Short-term bank borrowings as of December 31, 2022 consisted of the following:

Lender	Company	Rate	Issuance Date	Expiration Date	Amount-RMB	Amount-US$
Bank of Communications	Huadong	3.55%	3/9/2022	1/19/2023	4,000,000	579,946
Agricultural Bank of China	Huadong	3.40%	12/8/2022	12/7/2023	9,000,000	1,304,877
Jiangsu Yangzhou Rural Commercial Bank	Huadong	3.95%	2/17/2022	3/2/2023*	5,000,000	724,932
Bank of China	Huadong	3.55%	3/9/2022	1/19/2023*	5,000,000	724,932
Agricultural Bank of China	Yada	3.60%	12/8/2022	12/6/2023*	10,000,000	1,449,864
Industrial and Commercial Bank of China	Yada	3.70%	2/18/2022	2/21/2023*	9,000,000	1,304,877
Total					42,000,000	6,089,428

* These loans were renewed upon maturity.

Short-term bank borrowings as of December 31, 2021 consisted of the following:

Lender	Company	Rate	Issuance Date	Expiration Date	Amount-RMB	Amount-US$
Bank of Communications	Huadong	3.70%	11/1/2021	10/19/2022	5,000,000	784,610
Agricultural Bank of China	Huadong	3.70%	11/3/2021	11/3/2022	9,000,000	1,412,296
Jiangsu Yangzhou Rural Commercial Bank	Huadong	3.95%	2/25/2021	2/17/2022	5,000,000	784,609
Bank of China	Huadong	3.80%	3/3/2021	3/2/2022	5,000,000	784,609
Industrial and Commercial Bank of China	Yada	3.85%	2/19/2021	2/18/2022	9,000,000	1,412,296
Total					33,000,000	5,178,420

Interest expense was $191,198, $180,744 and $137,160 for the years ended December 31, 2022, 2021 and 2020, respectively.

The Company's short-term bank borrowings are pledged by the Company's assets and guaranteed by the Company's major shareholders Yongjun Liu, Yin Liu, Kai Liu and its subsidiary Yada.

The carrying values of the Company's pledged assets to secure short-term borrowings by the Company are as follows:

	December 31, 2022	December 31, 2021
	US$	US$
Buildings, net	2,777,379	2,499,131
Land use right, net	96,416	294,582
Total	2,873,795	2,793,713

10. Long-term bank loan

Lender	Company	Rate	Issuance Date	Expiration Date	Amount-RMB	Amount-US$
Bank of Communications	Huadong	3.50%	11/3/2022	4/25/2024	5,000,000	724,932
Total					5,000,000	724,932

On November 3, 2022, the Company signed a loan agreement with Bank of Communications to obtain a two-year loan of RMB 5 million ($724,932). The loan bears a floating interest rate of a benchmark rate (3.50%). Huada mortgages the property and land for guaranteed repayment of the loan. The principal shall be repaid on April 25, 2024.

Interest expense was $3,468, nil and nil for the years ended December 31, 2022, 2021 and 2020, respectively.

11. Taxes Payable

Taxes payable consisted of the following:

	December 31, 2022	December 31, 2021
	US$	US$
VAT payable	380,926	488,443
Income tax payable	690,824	1,521,767
Other tax payable	59,526	72,042
Total	1,131,276	2,082,252

12. Income Taxes

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gain. Additionally, upon payments of dividends to the shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong

Under the current Hong Kong Inland Revenue Ordinance, the Company's Hong Kong subsidiary, Kang Fu, is subject to 16.5% income tax on its taxable income generated from operations in Hong Kong. On December 29, 2017, Hong Kong government announced a two-tiered profit tax rate regime. Under the two-tiered tax rate regime, the first HK$2.0 million assessable profits will be subject to an 8.25% lower tax rate and the remaining taxable income will continue to be taxed at the existing 16.5% tax rate. The two-tiered tax regime becomes effective from the assessment year of 2018 and 2019, which is on or after April 1, 2018. The application of the two-tiered rates is restricted to only one nominated enterprise among connected entities. Kang Fu is nominated by the Company as the entity to apply the two-tiered rates among the group for the assessment years of 2022, 2021 and 2020.

PRC

Provisions for income tax are as follows:

	December 31, 2022	December 31, 2021	December 31, 2020
	US$	US$	US$
Provisions for current income tax	4,713,543	5,278,462	4,688,321
Provisions for deferred income tax	-	-	-
Total	4,713,543	5,278,462	4,688,321

The following is a reconciliation of the Company's total income tax expense to the income before income taxes for the years ended December 31, 2022, 2021 and 2020, respectively:

	2022	2021	2020
	US$	US$	US$
Income before income tax provision	18,129,648	26,228,041	23,733,576
Tax at the PRC EIT tax rates	3,758,113	5,605,035	4,724,933
Other	37,169	(13,086)	(28,392)
Tax effect of non-deductible expenses	1,660,869	226,222	313,006
Tax effect of R&D expenses additional deduction*	(742,608)	(539,709)	(321,226)
Income tax expense	4,713,543	5,278,462	4,688,321

* According to PRC tax regulations, an additional of 100% of current year R&D expenses may be deducted from tax income.

Under the Enterprise Income Tax Law ("EIT Law"), Foreign Investment Enterprises ("FIEs") and domestic companies are subject to Enterprise Income Tax ("EIT") at a uniform rate of 25%.

Huadong was entitled High and New Technology Enterprise ("HNTE") certificate and enjoyed preferential tax rate of 15% for a three-year validity period from November 30, 2016 and the HNTE certificate was renewed on November 22, 2019 with a three-year validity period. Thus, Huadong is eligible for a 15% preferential tax rate from January 1, 2016 to December 31, 2021.

The EIT Law also provides that an enterprise established under the laws of a foreign country or region but whose "de facto management body" is located in the PRC be treated as a resident enterprise for PRC tax purposes and consequently be subject to the PRC income tax at the rate of 25% for its global income. The Implementing Rules of the EIT Law define the location of the "de facto management body" as "the place where the exercising, in substance, of the overall management and control of the production and business operation, personnel, accounting, properties, etc., of a non-PRC company is located." Based on a review of surrounding facts and circumstances, the Company does not believe that it is likely that its entities registered outside of the PRC should be considered as resident enterprises for the PRC tax purposes.

The EIT Law also imposes a withholding income tax on dividends distributed by a FIE to its immediate holding company outside of the PRC. Kang Fu, which is the parent of Huada, Yada and Huadong, is therefore subject to a maximum withholding tax of 10% on dividends distributed by Huada, Yada and Huadong. In accordance with accounting guidance, all undistributed earnings are presumed to be transferred to the parent company and are subject to the withholding taxes. The presumption may be overcome if the Company has sufficient evidence to demonstrate that the undistributed dividends will be re-invested and the remittance of the dividends will be postponed indefinitely. As of December 31, 2022, the Company has determined that the undistributed earnings in Huada, Yada and Huadong will be re-invested into the subsidiary for the expansion of the Company's business in mainland China and hence the remittance of the dividends will be postponed indefinitely.

Uncertain tax positions

The Company evaluates each uncertain tax position (including the potential application of interest and penalties) based on the technical merits, and measure the unrecognized benefits associated with the tax positions. As of December 31, 2022, 2021 and 2020, the Company did not have any significant unrecognized uncertain tax positions.

13. Commitments and Contingencies

Operating lease

The Company has an operating lease to rent an office space in Shanghai. The lease term is 12 months, with the option to renew annually. Rent expense was $7,515, $7,839 and $7,324 and is included in general and administrative expenses for the years ended December 31, 2022, 2021 and 2020, respectively. The Company has renewed the same operating lease with a term from January 1, 2023 to December 31, 2023, with all other lease contents remaining the same.

Other commitments

The Company did not have other significant commitments, long-term obligations, or guarantees as of December 31, 2022, 2021 and 2020.

Contingencies

The Company is subject to legal proceedings and regulatory actions in the ordinary course of business. The results of such proceedings cannot be predicted with certainty, but the Company does not anticipate that the final outcome arising out of any such matter will have a material adverse effect on our consolidated business, financial position, cash flows or results of operations taken as a whole.

On February 4, 2022, Macias Gini & O'Connell, LLP ("Plaintiff") initiated a lawsuit in San Francisco Superior Court. Plaintiff, a certified public accounting firm based in the U.S., was hired by Kang Fu International Medical Co, and subsequently by Meihua International Medical Technologies Co, Ltd. (collectively, "Meihua"), to audit Meihua's consolidated financial statements for the 2018 and 2019 calendar years. Plaintiff seeks damages from Meihua for its alleged failure to pay for services rendered in the amount of $210,000, plus interest and attorneys' fees. Although Meihua denies plaintiff's allegations, on August 29, 2022, Meihua provided an initial settlement offer to Plaintiff. To date, Plaintiff has not substantively responded. The Court has set and continued multiple case management conferences based on Plaintiff's requests for continuances while the parties attempt to informally resolve the matter. No contingent liability has been recognized in relation to this matter since the outcome of the litigation is highly uncertain.

14. Statutory Surplus Reserves and Restricted Net Assets

Pursuant to laws applicable to entities incorporated in the PRC, the Company is required to make appropriations to certain reserve funds, comprising the statutory surplus reserve and the discretionary surplus reserve, based on after-tax net income determined in accordance with generally accepted accounting principles of the PRC ("PRC GAAP"). Appropriations to the statutory surplus reserve are required to be at least 10% of the after-tax net income determined in accordance with PRC GAAP until the reserve is equal to 50% of the entity's registered capital. Appropriations to the discretionary surplus reserve are made at the discretion of the Board of Directors. And as of December 31, 2022 and 2021, the Company did not have a discretionary surplus reserve. As of December 31, 2022, all of the Company's PRC subsidiaries reserves had reached 50% of their registered capital threshold and, as a result, the Company stopped being required to allocate after-tax profits to this reserve.

As a result of these PRC laws and regulations and the requirement that distributions by PRC entities can only be paid out of distributable profits computed in accordance with PRC GAAP, the PRC entities are restricted from transferring a portion of their net assets to the Company. Amounts restricted include paid-in capital and the statutory reserves of the Company's PRC subsidiaries. The aggregate amounts of capital and statutory reserves restricted which represented the amount of net assets of the relevant subsidiaries in the Company not available for distribution was $15,665,860 and $15,178,467 as of December 31, 2022 and 2021, respectively.

Under PRC laws and regulations, statutory surplus reserves are restricted to set-off against losses, expansion of production and operation and increasing registered capital of the respective company and are not distributable other than upon liquidation. The reserves are not allowed to be transferred to the Company in terms of cash dividends, loans or advances, nor allowed for distribution except under liquidation.

15. Related Party Transactions and Balances

Related Parties:

Name of related parties	Relationship with the Company
Yangzhou Yada Powder Metallurgy Co., Ltd.	An entity controlled by Kai Liu, son of Yongjun Liu
Jiangsu Zhida Pharmaceutical Co., Ltd.	An entity controlled by Kai Liu, son of Yongjun Liu
Shanghai Xinya Pharmaceutical Hanjiang Co., Ltd.	An entity controlled by Kai Liu, son of Yongjun Liu
Yangzhou Meihua Import and Export Co., Ltd.	An entity controlled by Kai Liu, son of Yongjun Liu

Related Party Sales

The Company sells products to its related parties and the sales amount from related parties for 2022, 2021 and 2020 are as follows:

Sales:

	For the Year Ended December 31,		
Name of related party	2022	2021	2020
Yangzhou Meihua Import and Export Co., Ltd.	$ 18,780	$ 51,750	$ 71,885
Yangzhou Yada Powder Metallurgy Co., Ltd.	-	347,737	669,583
Shanghai Xinya Pharmaceutical Hanjiang Co., Ltd.	10,416	176,414	67,101
Jiangsu Zhida Pharmaceutical Co., Ltd.	-	-	8,038
Total	$ 29,196	$ 575,901	$ 816,607

16. Subsequent Events

The Company has evaluated the impact of events that have occurred subsequent to December 31, 2022, through the date the consolidated financial statements were available to be issued, and concluded that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosure in the notes to the consolidated financial statements, except as follow:

Bank borrowing

As the date these consolidated financial statements were available to be issued, the Company has new bank borrowings in the amount of $2,609,755 (RMB 18 million) with interest rates ranging from 3.45-3.95% and has bank loan repayment of $2,609,755 (RMB 18 million).

New bank borrowing

Subsequent new bank borrowings consisted of the following:

Lender	Company	Rate	Issuance Date	Collateral/Security	Amount-RMB	Amount-USD
Jiangsu Yangzhou Rural Commercial Bank	Huadong	3.95%	1/30/2023	Yada, Yongjun Liu	5,000,000	724,932
Industrial and Commercial Bank of China	Yada	3.45%	2/17/2023	Properties of Yada	9,000,000	1,304,877
Bank of Communications	Huadong	3.50%	1/19/2023	Yongjun Liu, Yin Liu, Yada	4,000,000	579,946
Total					18,000,000	2,609,755

Repayment

Subsequent repayments on bank borrowings consisted of the following:

Lender	Company	Rate	Repayment Date	Collateral/Security	Amount-RMB	Amount-USD
Jiangsu Yangzhou Rural Commercial Bank	Huadong	3.95%	1/31/2023	Yada, Yongjun Liu	5,000,000	724,932
Bank of Communications	Huadong	3.55%	1/13/2023	Yongjun Liu, Yin Liu, Yada	4,000,000	579,946
Industrial and Commercial Bank of China	Yada	3.70%	2/16/2023	Properties of Yada	9,000,000	1,304,877
Total					18,000,000	2,609,755