Security Code: 300685 Stock Abbreviation: AmoyDx Announcement No: 2019-026

Abstract of 2018 Annual Report of Amoy Diagnostics Co., Ltd.

Notes:In the event of discrepancy between the English and Chinese version of this Abstract of 2018 Annual Report of Amoy Diagnostics Co., Ltd., the Chinese version shall prevail.

I. Important Notes

This abstract of annual report is extracted from the full text of the annual report. To comprehensively understand the operation results, financial status and future development planning of Amoy Diagnostics Co., Ltd. ("AmoyDx" or "the Company"), investors shall visit designated media of the China Securities Regulatory Commission to read the full text of the annual report carefully.

Objection Declaration of Directors, Supervisors and Senior Management Personnel

Name	Position	Reasons for Failure in Guaranteeing the Authenticity, Accuracy and Completeness

Declaration

All shareholders of the Company Other Than Directors Listed Below Attended the Meeting of the Board of Directors Organized to Consider this Annual Report

Name of Director Failing to Attend the Meeting	Position of Director Failing to Attend the Meeting	Reason for Absence in the Meeting	Name of the Proxy

The audit opinions for the financial statement expressed by BDO China Shu Lun Pan Certified Public Accountants LLP: standard and unqualified audit opinion.

Change in Accounting Firm in the Current Reporting Report: in the current year, the accounting firm was changed to BDO China Shu Lun Pan Certified Public Accountants LLP.

Prompts about Modified Audit Opinions

□ Applicable √ Not Applicable

Profit Distribution Plan for Common Shares or Increase Plan of Share Capital through Transfer from Accumulation Fund Reviewed by the Board of Directors

√ Applicable □ Not Applicable

The profit distribution plan for common shares reviewed and passed by the current meeting of the Board of Directors: take the total share capital on the equity registration date at the implementation date of the equity distribution plan for 2018 as the base number to distribute cash dividend of CNY 1.80 (tax included) and distribute 0 bonus share (tax included) for each 10 shares to all shareholders, and use the capital reserve to transfer 0 shares for each 10 shares to all shareholders.

Profit Distribution Plan for Preferred Shares in the Reporting Period Passed by the Meeting of the Board of Directors

□ Applicable √ Not Applicable

II. Basic Information of the Company

1. Company Profile

Stock Abbreviation	AmoyDx	Stock Code	300685
Stock Exchange where Stock Listed	Shenzhen Stock Exchange		
Contact Person and Contact Information	Secretary of the Board of Directors	Securities Affairs Representative	
Name	Luo, Jiemin	Yang, Shouqian	
Office Address	39 Dingshan Road, Haicang District, Xiamen	39 Dingshan Road, Haicang District, Xiamen	
Fax	0592-6806203	0592-6806203	
Telephone	0592-6806830	0592-6806830	
E-mail:	sid@amoydx.com	sid@amoydx.com	

2. Introduction to Main Business or Products in the Reporting Period

Since the establishment, the Company has devoted itself to the research, development and production of overall solutions/series of products for gene aberration detection for oncology precision medicine that could conform to applicable laws and industry specification to meet clinical demands of cancer patients. After continuous technical accumulation and construction of sales channels, the Company has developed a rich product pipeline with leading technologies. In addition, the Company has established R&D and sales teams with reasonable talent structure, outstanding expertise and strong technical capacity. The Company mainly engages in the R&D, production and sales of molecular diagnostic products for oncology precision medicine, and provides relevant detection services. Many technologies of the Company with independent property rights, including ADx-ARMS®, Super-ARMS® and ddCapture® are in leading positions worldwide in the industry. Based on the advantages of core technologies, the Company has successively developed 22 single-gene or multi-gene detection reagents, most of which are the first products approved by National Medical Products Administration (NMPA) in China and CE certified in European Union. In different external quality assessment programs including European Molecular Genetics Quality Network (EMQN) and Pathology Quality Control Center of the National Health Commission of the People's Republic of China (PQCC), products of the Company maintain exceptional accuracy rate and extremely high use rate for several consecutive years. Products of the Company are sold in hundreds of large and medium hospitals and scientific research institutions in more than 50 countries. As the diagnostic partner of many well-known pharmaceutical enterprises in the field of precision oncology, AmoyDx has won well-deserved reputation and wide recognition from customers.

The main businesses of the Company did not have any significant changes in the reporting period.

(I) Main Business and Products

1. Reagents for molecular testing

In order to provide full solution for oncology precision medicine, the Company has independently developed and produced a series of innovative products that have been examined and approved by relevant authorities. For example, the ARMS-based product line applicable to the detection of the tumor tissue specimen, Super-ARMS-based product line applicable to liquid biopsy, NGS-based product line applicable to multi-gene detection demands, as well as product lines for the extraction of FISH, IHC, nucleic acid and so forth, which can meet clinical demands of various tumor gene detection. In terms of cancer types covered, the Company has developed products for major cancers with precision medicine available, such as lung cancer, colorectal cancer, breast cancer, ovarian cancer, thyroid cancer, melanoma and so forth. In the field of lung cancer, the Company has made the full-journey management realized with single-gene and multi-gene testing products applicable to different types of specimens.

Products of the Company are mainly used to detect the gene variation status of cancer patients and thus provide scientific evidence for the prescription of appropriate medicine for personalized treatment proposals. For the most important genes in precision medicine like EGFR, KRAS, BRAF, ALK, PIK3CA, ROS1, NRAS, HER2, RET, MET, BRCA1/2 and so forth, the Company has developed 22 gene testing products of single-gene or multi-gene panel testing that have been approved by NMPA for clinical use, which are applicable to the detection of various types of specimens, including tissues and blood ctDNA. Based on the product series developed on the basis of multi-technology platforms like PCR, NGS and FISH that have been approved according to applicable laws and rules, the Company has provided reliable solutions to clinical gene testing with multi-technical platforms. In the reporting period, the operating income of detection reagent businesses was CNY 388.2279 million, witnessing a growth of 28.58% compared with that in the same period in the previous year.

As at the end of the reporting period, the Company owned 21 registration certificates for Class III Medical Devices (in vitro diagnostic reagents). In the period from the end of the reporting period to the disclosure date of the annual report in 2018, the Company achieved one additional registration certificate for Class III Medical Device (in vitro diagnostic reagent). Main products of the Company include:

Applicable Disease	Product Name	Description
Non-small cell lung cancer, colorectal cancer and so forth	EGFR Gene Mutation Detection Reagent Kit (ADx-ARMS® Technology)	EGFR Gene Mutation status is associated with the treatment effect of target therapy with Iressa, Tarceva, Conmana, Afatinib, and Ssimertinib..
	EGFR Gene Mutation Detection Reagent Kit (Super-ARMS® Technology)	
	EML4-ALK Fusion Gene Detection Reagent Kit	EML4-ALK Fusion Gene status is associated with the treatment effects of target therapy with Crizotinib.
	EML4-ALK Gene Fusion Detection Reagent Kit	ROS1 Gene Fusion status is associated with the treatment effects of target therapy with Crizotinib.
	Joint Detection Reagent Kit for EML4-ALK Gene Fusion and ROS1 Gene Fusion	Detect EML4-ALK Gene Fusion and ROS1 Gene Fusion on one-time basis.
	Joint Detection Reagent Kit for EGFR/ALK/ROS1 Gene Mutation	Detect EGFR/ALK/ROS1 Gene Mutation on One-time Basis.
	Detection Reagent Kit for mutation status of Five Genes (Fluorescence Real-time PCR Method)	Detect multiple key driver genes for lung cancer including genes like EGFR/ALK/ROS1/KRAS/BRAF.
	Joint Detection Reagent Kit for mutations of 10 Genes (Reversible Termination Sequencing Method)	Detect multiple key driver genes for lung cancer and colorectal cancer, including the gene of EGFR/ALK/ROS1/RET/KRAS/NRAS/PIK3CA/BRAF/HER2/MET.
	KRAS Gene Mutation Detection	Targeted drugs like Erbitux and Panitumumab have obvious effects for KRAS gene wild-type CRC patents,

	Reagent Kit	while have no effect to KRAS mutant patients. NSCLC patients with KRAS gene mutation has no response to targeted drugs like Gefitinib and Tarceva.
	NRAS Gene Mutation Detection Reagent Kit	Targeted drugs like Erbitux and Panitumumab have obvious effects for NRAS gene wild-type CRC patents, while have no effect to gene mutant CRC patients.
	Joint Detection Reagent Kit for KRAS/NRAS/PIK3CA/BRAF Gene Mutation	Detect KRAS/NRAS/PIK3CA/BRAF Gene Mutation on One-time Basis.
	Detection Reagent Kit for KRAS/NRAS Gene Mutation	Detect KRAS/NRAS Gene Mutation on One-time Basis.
	Joint Detection Reagent Kit for KRAS/NRAS/BRAF Gene Mutation	Detect KRAS/NRAS/BRAF Gene Mutation on One-time Basis.
Thyroid cancer, coloractal cancer, melanoma, lung cancer and so forth	Detection Reagent Kit for BRAF Gene V600E Mutation	BRAF gene mutation status affect efficacy of tyrosine kinase inhibition therapy.
Breast cancer, colorectal cancer, pancreatic cancer, gastric carcinoma and so forth	Detection Reagent Kit for HER-2 Gene Amplification	HER-2 Gene Amplification is associated with treatment effects of Herceptin and other targeted drugs.
	Detection Reagent Kit for Human BRCA1 and BRCA2 gene mutation (reversible terminator sequencing)	BRCA1/2gene mutation is associated with treatment effects of Olaparib and other relevant targeted drugs.
Multiple tumors	PIK3CA Gene Mutation Detection Reagent Kit	Drug resistance to tyrosine kinase inhibitor caused by PIK3CA gene mutation.

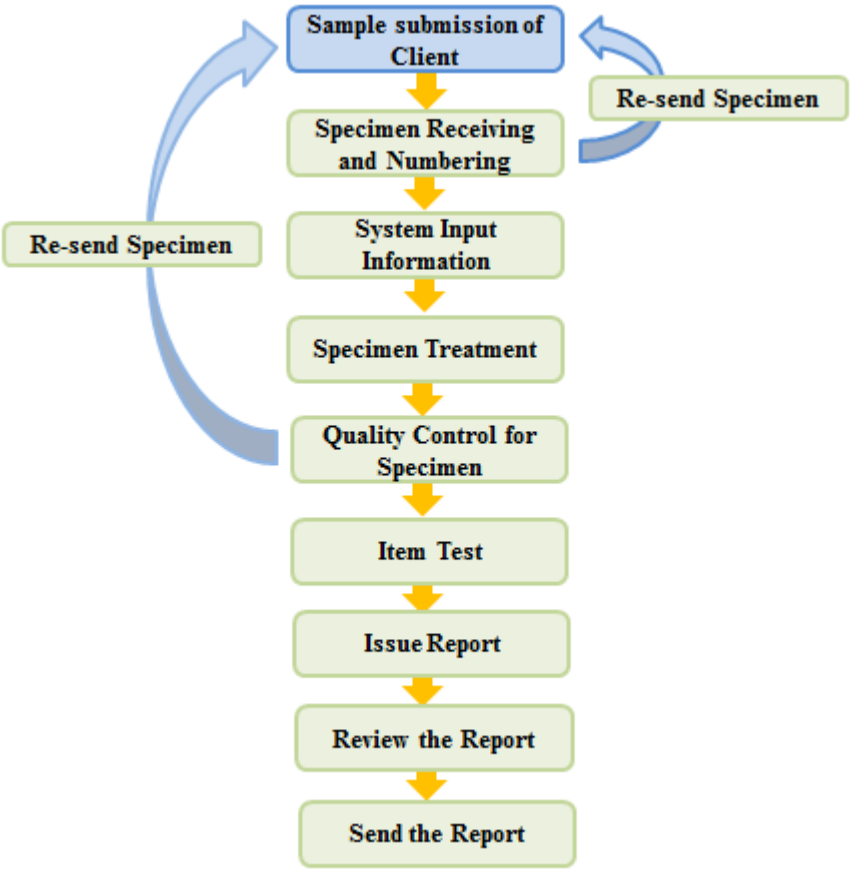
Notes: the above targeted drugs related diagnostics reagents of the Company have obtained the medical device registration certificates of NMPA.

From the end of the reporting period to the disclosure date of the annual report in 2018, the human BRCA1 and BRCA2 gene mutation (reversible terminator sequencing) of the Company obtained the registration certificate for Class III Medical Devices (in vitro diagnostic reagents) issued by NMPA. BRCA1 gene and BRCA2 gene are important tumor suppressor gene, which would play critical function in the repair of DNA damage. The mutations of BRCA genes have close connection with the occurrence and progress of multiple cancers like ovarian cancer, breast cancer, pancreatic cancer and so forth. By availing this opportunity, the Company would continuously strengthen the market development efforts in cancer diagnostics market like ovarian cancer, breast cancer, pancreatic cancer and so forth to further promote the development of diagnostics business for precision medicine. The approval of the product fills the compliance gap of clinical BRCA1/2 gene mutation detection in China, which drives the future development of the Company. So far, the Company has two Next Generation Sequencing (NGS)-based products approved by NMPA, which cover the detection needs of multiple tumor types.

2. Services for the molecular testing

AmoyDx Medical Institute, an independent third-party central lab established by the Company, owns Practicing License of Medical Institution of the People's Republic of China issued by the National Health Commission of the People's Republic of China and the CAP certification of American Association of Neuropathologists. Currently, the Lab has established seven top technical platforms for molecular testing service, including ADx-ARMS, Super-ARMS, Next Generation Sequencing (NGS), digital PCR (ddPCR), fluorescence in situ hybridization (FISH), first generation sequencing, Immune-Histochemical (IHC) and so forth. With the management and quality system implemented according to the running standard of CAP and CLIA detection laboratory, the Lab provides professional molecular testing services for the clinical studies of medical institutions and pharmaceutical enterprises and treatment of patients. In the reporting period, the operating income of detection services was CNY49.9847 million, witnessing a growth of 78.4% compared with that in the same period in the previous year.

According to the applicable clinical diseases, the detection services of the Company consist of detection of lung cancer, detection of colorectal cancer), detection of breast cancer, detection of thyroid, detection of lymphoma, detection of melanoma, detection of glioma, detection of ovarian cancer, detection of gastric cancer, detection of gastrointestinal stromal tumor (GIST) and so forth. According to the type of applicable clinic diseases, the service cycle would generally be from 3 to 10 working days. Specific service procedure for detection services is shown as below:



(II) Operation Model

The Company has independent and complete procurement, production and sale and continuously improves the operation responding to the market demands and development strategies of the Company.

1. Procurement

The Company implements centralized procurement management system. Purchase Department takes overall charge of the purchase and supply of raw and auxiliary materials to guarantee the normal ongoing of production and operation work of the Company. In accordance with the Supplier Audit System and requirements of the quality management system, Purchase Department would arrange preliminary assessment for suppliers within the scope of primary selection on the perspective of supply guarantee indicators like quality, price and supply schedule and the results of sample test and trial. After the countersignature of responsible person of Purchase Department and representative of the requesting department and approval of General Manager, Purchase Department shall determine the qualified supplier and incorporate it into the Qualified Supplier List to maintain a relatively stable cooperation relationship. For suppliers in the qualified supplier list, the Company arranges regular assessment according to the importance and use frequency of materials supplied, and decides whether the relevant supplier could have the qualification of being incorporated into the Qualified Supplier List of the next year according to the annual summary for assessment results.

2. Production

Main products of the Company are reagent products. The production procedure mainly includes reagent preparation, sub-packaging, outer packaging, inspection and so forth. According to product characteristics and customer demands, the Company implements production pipelines for multiple types of products, multiple specifications, small and multiple batches. The Company defined the production plan according to the projection of sale and guarantees the basic inventory level to meet the market demands. Production department of the Company shall prepare the monthly production plan according to the monthly sales plan prepared by Sales Department, the inventory level submitted by inventory management department and the production capacity and production progress of the production department. Production Department shall then release the monthly production plan to workshops of various product pipelines to arrange production.

The Company prepared the Production Procedure Management System to control various production processes and the personnel, materials, environment and equipment associated with the production process to improve the production efficiency and guarantee that the product quality reach the production requirements of the supervision authorities. The Company emphasizes the importance of safe production, and guarantee that the whole process should be under strict control in the production procedure.

3. Sale

The industry of molecular diagnostics for precision oncology where the Company engaged is an emerging hot field. The market is under rapid development stage and high level of professional marketing is required. Therefore, the Company sets the sale force of "integrating direct sales with distributors, and taking direct sales as the main force and distributors as the supplemental force" to guarantee the success of scientific promotion. The current sale model of the Company is suitable for the promotion of the Company products and has successfully addressed clinical needs. Moreover, the direct sales channel has superior advantages in the control of the sales channels, and conforms to the policy orientation for reducing the intermediate steps of the product distribution specified in the "Two-vote System" of medical reform.

(III) Key Drivers for the Sales Performance

With advantages in R&D capability, sales channels, brand effect and leading products, the Company firmly seizes up the opportunity brought by the rapid market development in the companion diagnostics for precision medicine, and take the orientation of clinical demands and patient benefits to continuously promote the innovation of technologies and launching of new products. In addition, the Company would strengthen the efforts in market promotion, sales team building, improving corporate governance structure and so forth to promote the sustainable, stable and healthy development of the main businesses and achieve the effective upgrading of the operation performance.

(IV) Analysis of the Industry which the Company Belongs to

The Company is in the segment of companion diagnostics in the in vitro diagnostics industry. As a category of in vitro diagnostic technologies associated with the clinical application of specific drugs, companion diagnostics help select the mostly suitable population for specific medicine from the patient population by detecting the biological markers like gene and protein in connection with clinical reactions for certain drugs. Companion diagnostics are the bases and preconditions for the precise use of targeted drugs, which could avoid the misuse of drugs, improve the living quality of patients and effectively save the social and medical cost.

Recently, the State Council, National Development and Reform Commission, National Health Commission of the People's Republic of China and many other national authorities have launched multiple policies to support the development of in-vitro diagnostics. For example, in the "13th Five-year" National Strategic Emerging Industry Development Planning, the State Council lists biological industry as an emerging industry and stresses to promote the medical industry to develop toward precision medicine and personalized medicine. In addition, it makes overall arrangement for the new diagnosis and treatment technologies for major genetic diseases, infectious diseases, malignant tumors and so forth. Medical

Administration and Management Bureau of the National Health Commission of the People's Republic of China released Guiding Principle for the Clinical Application of New Anti-tumor Drugs (Version 2018), Guidelines for Personalized Medicine Detection Technologies for Tumors (Provisional) and Guidelines for Gene Detection Technologies for Drug Metabolic Enzyme and Drug Targets (Provisional) to require the achievement of the standardization and normalization of gene detection for precision oncology.

Companion diagnostics is an important tool for the realization of precision medicine. Precision medicine is to determine the treatment proposal on the basis of the genetic information of each patient, predict the treatment effects and adverse reactions through understanding the differences in gene composition or gene expression between patients, and select the most appropriate treatment proposal for each patient. Along with the successful development and wide clinical application of targeted therapies and immunotherapys, it is expected that the field of cancer treatment may take a pioneering role in achieving precision medicine. According to Global Statistical Data for Cancer in 2018 of the International Cancer Research Center, it is estimated that there are 18.10 million of new cases with cancer and 9.60 million of death in the world in 2018 (calculated data cancer attack proportion of cancers in all ages and genders in the world, including the non-melanoma skin cancer). Among these 18.10 million new cases of cancer and 9.60 million of death, the new cancer cases and death cases in China were 3.804 million and 2.296 million respectively. Along with the aging of the population and extension of the age of cancer patients, the demand for products in companion diagnostics would maintain rapid growth year after year.

China set out to resolve the demands of residents to anti-cancer drugs since 2018. On one aspect, Chinese government gives priority support to the research and development of urgently needed anti-cancer drugs, and encourages the research and innovation of anti-cancer drugs with new targets and new mechanisms. On the other aspect, the government encourages the imitation and production of urgently needed anti-cancer drugs with patents reaching or close to maturity date. On the perspective of import, Chinese government implements no tariff on imported anti-cancer drugs from May 2018, which has largely reduced the VAT burden of anti-cancer drugs in the process of production and importation. To accelerate the import and market launching of innovative drugs, the application of clinical test is changed from "approval system" to "maturity default system". In October, 2018, a new round of medical insurance negotiation for anti-cancer drugs newly incorporated 17 varieties of new anti-cancer drugs, resulting in the 56.7% decrease in the payment standard compared with the average retail price, which largely reduce the drug use burden of cancer patients in China.

Along with the successive market launching of targeted drugs and immunotherapy drugs for cancers and the deduction in the drug use cost, companion diagnostics, as a required diagnosis procedure, would have a brighter market prospect. As per the forecast from MarketsandMarkets, companion diagnostics will

become one of the fastest growing sub-industries in the whole in-vitro diagnostics industry. It is estimated that the market size of companion diagnostics in the world would reach 6.51 billion US dollars, and the compound growth rate from 2017 to 2022 would reach as high as 20.1%, which would be far above the compound growth rate of the whole in-vitro diagnosis industry (5.5%).

(V) Position in the Industry

As an enterprise integrating with the R&D, production, sales and services of molecular diagnostics products, the Company is a world leading overall solution provider for tumor gene detection driven by independent innovation. The Company has world leading ADx-ARMS®, Super-ARMS® and ddCapture® technologies with independent intellectual property rights, and the most complete product lines for precision oncology that have got the certification of NMPA and CE certification of European Union. In several Chinese and international external quality assessment (EMQN, PQCC and so froth), products of the Company have maintained exceptional accuracy rate and extremely high use rate for several consecutive years.

3. Main Accounting Data and Financial Indicators

(1) Main Accounting Data and Financial Indicators in Recent Three Years

Whether the Company needs to make any retroactive treatment or representation for the accounting data in previous years
□ Yes √ No

Unit: Chinese Yuan (CNY)

	2018	2017	Increase or Decrease Compared with That in the Previous Year	2016
Operating Income	439,031,481.74	330,371,305.09	32.89%	252,987,005.08
Net Profit Belongs to the Shareholders of Listed Company	126,737,914.51	94,065,765.39	34.73%	67,033,948.60
Net Profit after Deduction of the Non-recurring Profit and Loss that Belongs to the Shareholders of Listed Company	108,113,554.39	80,076,400.94	35.01%	48,237,200.14
Net Cash Flow Generated from Operating Activities	93,448,159.37	91,890,087.67	1.70%	32,184,851.49
Basic Earnings per Share (Yuan/share)	0.88	0.76	15.79%	0.62
Diluted Earnings per Share (Yuan/share)	0.88	0.76	15.79%	0.62
Weighted Average Return On Equity	17.79%	20.54%	-2.75%	24.43%
	End of 2018	End of 2017	Increase or Decrease at the End of the Year Compared with That at the End of the Previous Year	End of 2016
Total Assets	818,746,842.78	694,848,313.15	17.83%	353,300,881.91
Net Assets Belongs to the Shareholders of Listed Company	756,739,590.55	649,201,676.04	16.56%	307,905,910.65

(2) Main Accounting Data by Quarter

Unit: Chinese Yuan (CNY)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Operating Income	88,902,671.24	113,590,048.36	107,994,624.09	128,544,138.05
Net Profit Belongs to the Shareholders of Listed Company	24,977,042.71	44,598,531.43	26,297,189.54	30,865,150.83
Net Profit after Deduction of the Non-recurring Profit and Loss that Belongs to the Shareholders of Listed Company	21,112,025.62	38,572,359.45	23,191,199.20	25,237,970.12
Net Cash Flow Generated from Operating Activities	19,622,745.53	35,323,943.27	19,838,271.05	18,663,199.52

Whether the above financial indicators or other total amount have any major difference with relevant financial indicators indicated in any quarterly report and semi-annual report

□ Yes √ No

4. Information about Share Capital and Shareholders

(1) Information Sheet about Shareholders of Common Shares, Number of Shareholders of Preferred Shares with Recovered Voting Rights, and Shareholding of Top Ten Shareholders

Unit: Share

Total Number of Shareholders of Common Shares at the End of the Reporting Period	9,758	Total Number of Shareholders of Common Shares at the End of the Month before the Disclosure Date of the Annual Report	9,086	Total Number of Shareholders of Preferred Shares with Recovered Voting Rights at the End of the Reporting Period	0	Total Number of Shareholders of Preferred Shares at the End of One Month before the Disclosure Date of the Annual Report	0

Shareholding Status of Top 10 Shareholders

Shareholder Name	Shareholder Nature	Shareholding Proportion	Shareholding Quantity	Quantity of Stocks with Restriction on Sales	Pledge or Freeze Status	
					Share Status	Quantity
Superior View Investment Limited	Overseas Legal Person	23.58%	33,961,680	33,961,680		
Xiamen Haicang District Yixiang Investment Partnership (Limited Partnership)	Domestic Non-state-owned Legal Person	9.49%	13,667,400	13,667,400		
Xiamen Haicang District Keying Investment Partnership (Limited Partnership)	Domestic Non-state-owned Legal Person	8.79%	12,656,520	0		
OrbiMed Asia Partners Ⅱ,L.P.	Overseas Legal Person	6.12%	8,819,500	0		
Fujian Longyan Xinlianxin Investment Partnership (Limited Partnership)	Domestic Non-state-owned Legal Person	5.56%	7,999,994	0	Pledge	3,857,695
Xiamen Longbai Hongxin Venture Investment Partnership (Limited Partnership)	Domestic Non-state-owned Legal Person	4.87%	7,018,920	0		
Xiamen Haicang Dingsheng Investment Partnership (Limited Partnership)	Domestic Non-state-owned Legal Person	3.66%	5,269,320	5,269,320		
QM18 LIMITED	Overseas Legal Person	2.86%	4,123,120	0		
Songzhou Qiming Equity Investment Partnership Enterprise (Limited Partnership)	Domestic Non-state-owned Legal Person	2.27%	3,268,780	0		
Xiamen Dehuisheng Equity Investment Partnership (Limited Partnership)	Domestic Non-state-owned Legal Person	1.53%	2,205,244	0		
Description for the related party relationship or concerted action of		Xie Meiqun, executive partner of Xiamen Haicang District Yixiang Investment Partnership (Limited Partnership), and Luo Fei, executive				

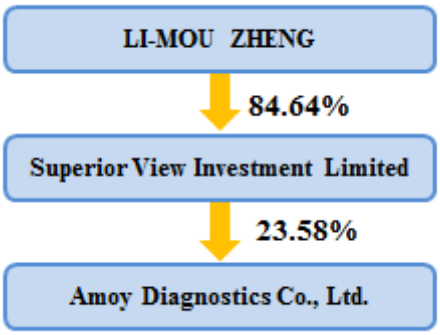
above shareholders	partner of Xiamen Haicang Dingsheng Investment Partnership (Limited Partnership), are in mother and daughter relationship. Xiamen Haicang Dingsheng Investment Partnership (Limited Partnership) is a shareholding platform of employees of the Company. Except for the above relationship described, the above shareholders do not have any related party relationship or concerted actions as specified in the Management Method for the Acquisition of Listed Enterprises.

(2) Information Sheet about Total Number of Shareholders of Preferred Shares and Shareholding of Top Ten Shareholders of Preferred Shares

□ Applicable √ Not Applicable

The Company did not have any shareholder of preferred shares holding any shares of the Company in the current reporting period.

(3) Disclosure of the Property Rights and Control Relationship between the Company and Actual Control Person in the Form of Block Diagram



5. Information about Corporate Bonds

Whether the Company has any corporate bonds under public offer listed in any securities exchange that had not matured on the approval date of the annual report or had matured on the annual report but failed to honor in full amount

No

III. Discussion and Analysis about Operation Status

1. Operation Overview in the Reporting Period

Whether the Company needs to meet disclosure requirements of any special industry

Yes

Medical Device Industry

In 2018, with advantages in R&D capability, sales channels, brand effect and leading products, the Company firmly seizes up the opportunity brought by the rapid market development in the companion diagnostics of precision medicine, and take the orientation of clinical demands and patient benefits to continuously promote the innovation of technologies and launching of new products. In addition, the Company would strengthen the efforts in market promotion, sales team building, improving of corporate governance structure and so forth to promote the sustainable, stable and healthy development of the main businesses and achieve the effective upgrading of the operation performance.

In the reporting period, the Company achieved the operating income of CNY439.0315 million,

witnessing a growth of 32.89% compared with that in the same period of the previous year; the amount of net profit belonging to owners of parent company achieved was CNY126.7379 million, witnessing a growth of 34.73% compared with that in the same period of the previous year; the amount of net profit belonging to owners of patent company after deducting non-recurring profit and loss achieved was CNY108.1136 million, witnessing a growth of 35.01% compared with that in the same period of the previous year.

In the reporting period, the Company completed below important work:

(I) R&D and Products

1. Created "Dual-center for Research and Development" to strength technological innovation and facilitate the future development of the Company

The creation of "Dual-center for R&D" is a major strategic measure taken by the Company for future development. With advantages of Shanghai and Xiamen, the Company took the orientation of clinical demands and patient benefits to strengthen the R&D input, establish innovation system appropriate with the development stage of the Company, and set a sound foundation for attracting the talents, R&D of new technologies and optimization of current technologies.

In the reporting period, the Company completed the reconstruction and expansion of Shanghai R&D Center and Xiamen R&D Center. In addition, Shanghai Xiawei Central Laboratory passed the certification of CAP (College of American Pathologists), which indicated that the quality management system and the standardization and accuracy of the technologies of Shanghai Xiawei Central Laboratory had reached the international advanced level.

2. Insist on continuous input in R&D, and bring superior registered products to win the market

In recent years, the proportion of R&D input taken in the operating income is maintained at the level above 15%. In the reporting period, the R&D input of the Company was CNY78.3363 million, which increased for 54.12% compared with that in the same period of the previous year. The R&D input took 17.84% of the operating income of the period. With such input, the Company acquired the authorization of 6 domestic patents. Derivative and probe used to detect the human EGFR gene mutation and their use method won the first prize of patent award of Fujian in 2017.

It is known that the transformation from single-gene detection to multi-gene joint detection, from tissue detection to the concurrent detection of blood and tissue and from single drug use instructions to the full disease process management is the development trend of companion diagnostics for tumors. For this consideration, the Company insists on taking clinical demands and patient benefits as the orientation to continuously promote the innovation in technologies and market launching of new products. In the reporting period, multiples new products developed on the basis of the technological platforms with independent intellectual property rights like ADx-ARMS®, Super-ARMS® and ddCapture® were approved by NMPA for market launching. These products mainly include:

ctDNA Detection Reagent Kit was approved as per the review conducted according to the standard for reagents of companion diagnostics. The kit for human EGFR mutant detection (Multiple Fluorescence Real-time PCR Method) is a ctDNA detection kit approved by NMPA through special examination and approval channel for innovative medical device by reference to the standard for reagents of companion diagnostics of FDA for the first time. With the application of the Super-ARMS® technology, a new generation of ctDNA gene mutation detection technology with independent intellectual property rights, the product inherits the advantages of ADx-ARMS® technology of simple, rapid, accurate, easy for popularization and so forth. The sensitivity of the product could reach 0.2%. The product could be used to detect EGFR gene mutation status in the blood of advanced non-small cell lung cancer (NSCLC) patients and screen patients that are suitable for accepting the treatment of EGFR targeted drugs from the first generation to the third generation.

Multi-gene detection products for lung cancer were approved. Detection kit (Fluorescence Real-time PCR Method) for the mutation of five genes could detect multiple core driving genes of lung cancer, including EGFR, ALK, ROS1, KRAS and BRAF. In keeping up with the development trend of precision medicine for tumors and based on the PCR technology platform, the Company launched several products that could realize joint detection for multiple genes to meet the demands changes of clinical practices for lung cancer to the detection of gene targets.

NGS products for two cancers, five companion diagnostics and 10 genes were approved. Human 10-gene mutation joint detection reagent box (reversible terminator sequencing) products for two cancers, five companion diagnostics and 10 gene were approved, which could cover the gene mutation detection required targeted drugs on market or proposed to be launched on the market for the treatment of lung cancer and colorectal cancer.

Many products developed on the basis of multi-technology platforms like PCR, NGS and FISH have been approved by applicable laws, which would provide compliant and all-around detection services with multi-technical platforms.

3. Keep in step with the industry development trend, and prepare products for the future

In recent years, Immunology Oncology Therapy (I-O Therapy) has become a hot research field in the treatment of tumors. I-O therapy is to withstand tumor cells by activating the immunological competence of the patient, which would constitute the footstone for future tumor treatment together with operative treatment, radio-therapy and targeted therapy. Along with the continuous diversification of targeted drugs and immunotherapy drugs for cancers and the deduction in the drug use cost, companion diagnostics, as a required diagnosis procedure, will have a bright market prospect.

The Company and its subsidiaries have already made strategic arrangement for the research work of

relevant markers and data analysis software associated with immunotherapy drugs for cancers, and established IVD product research team and data analysis software development team to conduct comprehensive evaluation and data accumulation for relevant biological markers associated with immunotherapy and meet the urgent clinical demands of detection and data analysis. In 2018, the Company reassign some fund raised into the research project for the diagnostic products and software for immunotherapy. With the base of artificial intelligence and medical big data, the Project is to develop new diagnostic products and supporting data analysis software on the basis of current markers (like PDL1, MSI, TMB and so forth) associated with immunotherapy drugs.

For the consideration of long-term development strategy, the Company increased the capital investment on Universal Sequencing Technology Corporation (hereinafter short for "UST Company"). UST Company is a high biotechnology enterprise specializing in R&D and industrialization of gene sequencing platforms. Products of this enterprise are still under the R&D and industrialization promotion stage. Mass production and external sales have not been achieved yet.

(II) Marketing Services

1. Deepen the market innovation, strengthen the marketing construction and scientific promotion, and win the first chance for the future with differential advantages

On the basis of current sales channels in Chinese domestic market, we would further strengthen the construction of marketing network, enlarge the market coverage rate and penetration rate and improve the direct-sales network covering the whole country. With constant insistence on the technical marketing, scientific promotion and brand marketing, the Company will focus on the innovative products like Super-ARMS® blood EGFR, Aihuijian ™, Weihuijian ™ and so forth to promote them through market launching event of new products, scientific conference, technical training programs and so forth. Meanwhile, we would take full advantage of multiple Internet promotion tools like official website, WeChat account, professional forums and so forth to acquire the recognition of doctors and patients for compliance products of the Company. The Company will continue utilizing the exclusively approved multi-gene joint detection products and EGFR testing products of Super-ARMS® to create the differential competitive edge.

In the reporting period, the operating income from domestic business was CNY393.1486 million, witnessing a growth of 31.40% compared with that in the same period in the previous year. As at the end of the reporting period, the Company has a sales team with more than 200 members to take charge of the marketing services for the national market. In addition, a full-time technical team provided professional technical services to customers. Currently, products of the Company have been sold in more than 400 large and medium-sized medical institutions.

2. Continue developing the overseas market with good progress

On the aspect of international market, the Company put more efforts in the market development to

improve the connection between international distributors and the Company, strengthened the cooperation with cancer experts, sales terminals and pharmaceutical enterprises, and actively participated in the clinical test for original drugs of pharmaceutical enterprises to promote the products of the Company to be approved as companion diagnostics reagent for new drugs. The Company also provided rapid and efficient product training programs, and organized product training classes in key markets to provide product training and technical support for key customers. We expanded the coverage of the logistics center in Europe, and actively participated in international meetings to further establish the brand of AmoyDx and serve for the international strategy of the Company.

In the reporting period, the operating income from overseas businesses was equivalent to CNY45.8829 million, witnessing a growth of 47.24% compared with that in the same period in the previous year. In the annual meeting of international distributors in 2018 in Shanghai, more than 50 distributor representatives from different countries reviewed and discussed the development situation and strategies of AmoyDx international business, shared the experiences and exchanged market information and opportunities in different market. In 2018 AmoyDx ROS1 detection kit was approved in South Korea and Taiwan with the specific information shown as follows:

ROS1 companion diagnostics kit was approved in South Korea and Taiwan, China. Before that, the product has been approved by Chinese NMPA, CE-marked to European Union and approved by Japanese PMDA. Moreover the product has been listed in National Health Insurance in Japan. The approval of the product in South Korea and Taiwan will further enhance the market competitiveness of the Company in overseas market in addition to the Mainland China, which will have great positive impact to the future development of the Company.

3. Strengthen the technical service team to provide rapid response or service demands of customers

In the reporting period, the Company further strengthened the construction of the technical service database and marketing network. An efficient technical service team could accurately analyze and solve relevant feedbacks from customers and end-users and thus win the reputation in the industry. Moreover, it is also beneficial for the Company to timely learn about the new demands and new trends of the market.

(III) Corporate Governance

1. Actively optimized the management and further improved the operation efficiency

In the reporting period, the Company continued the strict implementation of the management philosophy of “Quality, Cost, and Efficiency”, and actively utilized the information technology to promote the delicacy management, continuously optimized the internal control, management procedure and operation mechanism for purchase, production, R&D and sales to guarantee the legality and compliance of the operation management of the Company and the orderly ongoing of the operation activities. The Company

also strengthened the financial control approaches to intensify the management for payment collection and budget control in order to promote the stable and healthy development of the Company. In 2018, the sales expense ratio was 39.15%, decreased 0.12% compared with 2017; the management expense ratio was 5.87%, decreased 1.97%.

2. Continuously promoted the corporate culture to enhance the staff cohesion

The Company insisted on the talent strategy of "centering on Fighter" to exert more efforts in talent attraction and internal training to provide human resource foundation for the overall development strategy of the Company. On one aspect, we recruited talents for R&D, marketing, management through different channels, further improved the incentive mechanism with high market standard, and endeavored to create a stable and high-quality professional team at all levels. In the reporting period, the Company newly hired 126 employees, most of them were in R&D and sales. On the other aspect, the Company strengthened the on job training for all employees. The Company organized multiple training programs on technology, management, production and sales to improve the comprehensive qualities of employees. Meanwhile the Company organized diversified corporate cultural activities centering on the brand value of "life caring, pursuit of excellence, continuous innovation and win-win cooperation", the Company strengthened the corporate culture construction through multiple perspectives, approaches and channels to strengthen the relations between the Company and the employees. In 2018 the Company established a library, fitness room and activity room for the employees to provide good environment for study, leisure and entertainment.

3. Actively undertook social responsibilities to foster superior brand

The Company carried out the enterprise tenet of "AmoyDx is the right diagnostic partner for cancer treatment", which indicates that the Company will insist on innovation, improvement of products and services to continuously contributes to the health of the public. In the reporting period, the Company actively took its social responsibility and took advantage of its professional strengths to continuously provide accurate, repaid and reliable diagnostic services to cancer patients, which had effectively avoided the misuse and abuse of targeted drugs and saved a lot of social medical cost. At the same time, the Company also positively participated in different charity and social welfare programs including "Donation Project for the Medical Funds of Poverty-stricken Towns and Villages in Jiange County of Sichuan", "Love in Changdu and Warmth in Winter" and so forth, to faithfully fulfill the social responsibilities.

2. Whether the main businesses of the Company experienced any major changes in the reporting period

□ Yes √ No

3. Information about the products with over 10% of sales revenue or the profit of the Company

√ Applicable □ Not Applicable

Unit: Yuan

Product Name	Operating Income	Operating Profit	Gross Margin	Increase or Decrease of Operating Income Compared with that of the Same Period in the Previous Year	Increase or Decrease of Operating Profit Compared with that in the Same Period of the Previous Year	Increase or Decrease of Gross Margin Compared with that of the Same Period in the Previous Year
Income from Diagnostic Reagents sales	388,227,871.50	127,269,923.53	92.91%	28.58%	30.94%	-1.34%
Income from Diagnostic Services	49,984,721.86	16,386,128.34	77.47%	78.40%	81.67%	5.40%

4. Whether the Company has any seasonable or periodic features in operation that need special attention

□ Yes √ No

5. Description of major changes in operating income, operating cost, or total amount or composition of net profits belonging to shareholders of common shares of listed enterprises

√ Applicable □ Not Applicable

In the reporting period, the Company achieved the operating income of CNY439.0315 million, witnessing a growth of 32.89% compared with that in the same period of the previous year; the amount of net profit belonging to owners of parent company achieved was CNY126.7379 million, witnessing a growth of 34.73% compared with that in the same period of the previous year; the amount of net profit belonging to owners of patent company after deducting non-recurring profit and loss achieved was CNY108.1136 million, witnessing a growth of 35.01% compared with that in the same period of the previous year; In the reporting period, in accordance with the long-term development strategy and the annual operation plan and by virtue of its advantages in R&D capacity, sales channels, brand influence and leading products, the Company firmly seized up the opportunity brought by the rapid market development in the companion diagnostics for precision medicine, and took the orientation of clinical demands and patient benefits to continuously promote the innovation of technologies and launch new products. In addition, the Company put more efforts on market promotion, sales team construction, improvement of organizational structure and management system to achieve the sustainable, stable and healthy development of the main businesses and the effective upgrade of the overall performance.

6. Information about Confronted Suspension and Termination of Public Listing

□ Applicable √ Not Applicable

7. Relevant Issues Involving with Financial Statements

(1) Information about changes in accounting policies, accounting estimates and accounting method compared with the financial statements in the previous year

√ Applicable □ Not Applicable

In 2018, the Ministry of Finance released the Notice about Modifying and Printing the Formats of Financial Statements of General Enterprises in 2018 (Finance Accounting No. [2018] 15), which made certain amendments to the formats of financial statements of general enterprises. According to the amendment requirements of the above accounting standard, the Company needs to make corresponding changes to relevant contents in the accounting policies, and prepare financial statements of the Company according to the formats of financial statements for general enterprises specified in such notice. Main impacts for the implementation of the above regulation are shown as below:

Contents and Reasons of Changes in Accounting Policies	Name of Subjects Being Influenced and Corresponding Influence Amount
(1) In the balance sheet, the subject "Notes Receivables" and "Accounts Receivables" were combined into the subject of "Notes Receivable and Accounts Receivable"; "Notes Payable" and "Accounts Payable" are combined into the subject of "Notes Payable and Accounts Payable"; "Interest Receivable" and "Dividend Receivable" were listed under the subject of "Other Receivables"; "Interest Payable" and "Dividend Payable" were listed under the subject of "Other Payables"; "Disposal of Fixed Assets" was listed under the subject of "Fixed Assets"; "Engineering Material" was listed under the subject of "Construction in Progress"; and "Special Payable" was listed under the subject of "Long-term Payables". Corresponding adjustment was also made for comparative data	"Notes Receivables" and "Accounts Receivables" were combined into the subject of "Notes Receivable and Accounts Receivable". The amount in the current period was 189,049,121.01 Yuan and the amount in the previous period was 142,686,675.64 Yuan. "Notes Payable" and "Accounts Payable" are combined into the subject of "Notes Payable and Accounts Payable". The amount in the current period was 13,016,706.67 Yuan and the amount in the previous period was 9,603,823.22 Yuan.
(2) The subject "R&D Expenses" was newly added in the Income Statement, and the R&D Expenses under original "Management Expenses" was reclassified into the subject of "R&D Expenses" for separate listing; newly added subjects "Including: Interest Expense" and "Interest Income" under the subject of Financial Expenses in the Income Statement. Corresponding adjustment was also made for comparative data	Adjust to decrease the amount of Management Expenses in the current period for 78,336,287.73 Yuan, and the amount decreased for the previous period was 50,828,141.89 Yuan, which was reclassified into the subject of "R&D Expenses".

The changes in the accounting policies did not have any significant influence on the financial status, operation results and cash flow of the Company.

(2) Description about retrospective restatement made in the current reporting period for major previous accounting errors

□ Applicable √ Not Applicable

The Company did not have any retrospective restatement for prior accounting errors in the reporting period.

(3) Information about changes in consolidation scope of financial statements compared with the financial statements in the previous year

□ Applicable √ Not Applicable

The Company did not have any changes in the consolidation scope of financial statements in the current reporting period.