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INTRODUCTION

Except where the context otherwise indicates and for the purpose of this annual report only:

- “ADSs” refers to the American depositary shares, each representing five of our ordinary shares;
- “China” or “PRC” refers to the People’s Republic of China, excluding, for the purpose of this annual report only, Taiwan, Hong Kong and Macau;
- “Greater China,” with respect to our collaboration with CStone Pharmaceuticals (Suzhou) Co., Ltd. (“CStone”), refer to Mainland China, Taiwan, Hong Kong and Macau;
- “Genetron” refers to Genetron Holdings Limited, an exempted company incorporated under the laws of the Cayman Islands with limited liability;
- “IVD” refers to *in vitro* diagnostics products, including platforms and assays;
- “LDT” refers to laboratory developed tests which examine samples taken from the human body, such as body fluids (blood, urine, cerebrospinal fluid, etc.) and tissue, and are conducted in our laboratories.
- “ordinary shares” refers to our ordinary shares of par value US\$0.00002 per share;
- “PRC Subsidiaries” refers to Genetron (Tianjian) Co., Ltd. and Genetron (Wuxi) Business Management Co., Ltd., which are the primary beneficiary of the respective VIE, in the context of describing of their activities;
- “RMB” or “Renminbi” refers to the legal currency of the People’s Republic of China;
- “US\$,” “dollars” or “U.S. dollars” refers to the legal currency of the United States;
- “we,” “us,” “our Company,” or “our” refers to Genetron Holdings Limited and its subsidiaries, and, in the context of describing our consolidated financial information, business operations and operating data, its consolidated VIEs and their subsidiaries; and
- “variable interest entities,” or “VIEs,” refers to Genetron Health (Beijing) Co., Ltd. and Genetron (Wuxi) Biotech Co., Ltd. in the context of describing their activities and contractual arrangements with us.

We present our financial results in RMB. We make no representation that any RMB or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or RMB, as the case may be, at any particular rate, or at all. The PRC government imposes control over its foreign currency reserves in part through direct regulation of the conversion of RMB into foreign exchange and through restrictions on foreign trade. This annual report contains translations of certain foreign currency amounts into U.S. dollars for the convenience of the reader. Unless otherwise stated, all translations of Renminbi into U.S. dollars were made at the rate at RMB6.3726 to US\$1.00, the exchange rate as set forth in the H.10 statistical release of the Board of Governors of the Federal Reserve System in effect as of December 30, 2021.

FORWARD-LOOKING INFORMATION

This annual report on Form 20-F contains forward-looking statements that reflect our current expectations and views of future events. All statements other than statements of historical facts are forward-looking statements. These forward-looking statements are made under the “safe harbor” provision under Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and as defined in the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. In some cases, you can identify these forward-looking statements by terminology such as “may,” “will,” “expect,” “anticipate,” “aim,” “estimate,” “intend,” “plan,” “believe,” “is/are likely to,” “potential,” “continue” or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to:

- our goals and growth strategies;
- our future business development, results of operations and financial condition;
- relevant government policies and regulations relating to our business and industry;
- our expectations regarding demand for and market acceptance of our diagnosis services and products, cancer early screening services and our IVD products and our ability to expand our customer base;
- our ability to obtain and maintain regulatory approvals from the NMPA, the NCCL and have our laboratory certified or accredited by authorities including the CLIA and the CAP;
- our ability to obtain and maintain intellectual property protections for our technologies and our continued research and development to keep pace with technology developments;
- impacts of the COVID-19 pandemic;
- general economic and business condition in China; and
- assumptions underlying or related to any of the foregoing.

We would like to caution you not to place undue reliance on these forward-looking statements and you should read these statements in conjunction with the risk factors disclosed in “Item 3. Key Information—3. D. Risk Factors” of this annual report and other risks outlined in our other filings with the Securities and Exchange Commission, or the SEC. Those risks are not exhaustive. We operate in an evolving environment. New risks emerge from time to time and it is impossible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in any forward-looking statement. We qualify all of our forward-looking statements by these cautionary statements.

You should not rely upon forward-looking statements as predictions of future events. We do not undertake any obligation to update or revise the forward-looking statements except as required under applicable law. You should read this annual report and the documents that we reference in this annual report completely and with the understanding that our actual future results may be materially different from what we expect.

EXPLANATORY NOTE

Investing in our securities involves a high degree of risk. Please carefully consider the risks discussed under the section entitled “Item 3. Key Information—D. Risk Factors” in this annual report. We provide the following disclosure to help investors better understand our corporate structure, operations in China and the associated risks.

As used in this annual report, (i) “we,” “us,” “our Company,” or “our” refers to Genetron Holdings Limited and its subsidiaries, and, in the context of describing our consolidated financial information, business operations and operating data, its consolidated VIEs and their subsidiaries; (ii) “Genetron” refers to Genetron Holdings Limited, an exempted company incorporated under the laws of the Cayman Islands with limited liability; (iii) “PRC Subsidiaries” refers to Genetron (Tianjin) Co., Ltd., the primary beneficiary of Genetron Health (Beijing) Co., Ltd., and Genetron (Wuxi) Business Management Co., Ltd., the primary beneficiary of Genetron (Wuxi) Biotech Co., Ltd., in the context of describing their activities; and (iv) “variable interest entities,” or “VIEs,” refers to Genetron Health (Beijing) Co., Ltd. and Genetron (Wuxi) Biotech Co., Ltd. in the context of describing their activities and contractual arrangements with us. The VIEs primarily conduct operations in China, and the VIEs are consolidated for accounting purposes but are not entities in which we own equity.

Our Corporate Structure and Operation in China

Genetron Holdings Limited is a Cayman Islands holding company. It conducts its operations in China through its PRC subsidiaries, the VIEs, and subsidiaries of the VIEs. To comply with PRC laws and regulations, we established the VIEs, Genetron Health (Beijing) Co., Ltd. (“Genetron Health”) and Genetron (Wuxi) Biotech Co., Ltd., to conduct precision oncology services business activities.

However, we and our direct and indirect subsidiaries do not, and it is virtually impossible for them to, have any equity interests in the VIEs in practice as current PRC laws and regulations impose certain restrictions or prohibitions on foreign ownership of companies that engage in the field of technology development and applications relating to human stem cells and genomic diagnosis and treatment. Therefore, we exercise effective control over Genetron Health through contractual arrangements among Genetron (Tianjin) Co., Ltd., Genetron Health and shareholders of Genetron Health; and we exercise effective control over Genetron (Wuxi) Biotech Co., Ltd. through contractual arrangements among Genetron (Wuxi) Business Management Co., Ltd, Genetron (Wuxi) Biotech Co., Ltd. and its shareholders. This structure is also designed to replicate substantially the same economic benefits as would be provided by direct ownership. As a result of these contractual arrangements, our PRC Subsidiaries are the primary beneficiaries of the VIEs and, therefore, we have consolidated the financial results of the VIEs in our consolidated financial statements in accordance with IFRS. For a detailed description about such structure and the relevant contractual arrangements, see “Item 4. Information on the Company—4.C. Organizational Structure.”

The VIEs are owned by certain nominee shareholders, not us. All of these nominee shareholders are also beneficial owners of the Company. Investors in our ADSs are purchasing equity securities of a Cayman Islands holding company rather than equity securities issued by our subsidiaries and the VIEs. Our contractual arrangements with the VIEs and their respective shareholders have not been tested in a court of law in the PRC, and investors who are non-PRC residents may not directly hold equity interests in the VIEs under current PRC laws and regulations. If the PRC government deems that our contractual arrangements with the VIEs do not comply with PRC regulatory restrictions on foreign investment in the relevant industries, or if these regulations or the interpretation of existing regulations change in the future, we could be subject to material penalties or be forced to relinquish our interests in those operations or otherwise significantly change our corporate structure. We and our investors face significant uncertainty about potential future actions by the PRC government that could affect the legality and enforceability of the contractual arrangements with the VIEs and, consequently, significantly affect our ability to consolidate the financial results of the VIEs and the financial performance of our Company as a whole. Our ADSs may decline in value or become worthless if we are unable to effectively enforce our contractual control rights over the assets and operations of the VIE that conduct a significant portion of our business in China. See “Item 3. Key Information—3.D. Risk Factor—Risks Related to Our Corporate Structure” for detailed discussion.

We face various legal and operational risks and uncertainties as a company based in and primarily operating in China. The PRC government has significant authority to exert influence on the ability of a China-based company, like us, to conduct its business, accept foreign investments or be listed on a U.S. stock exchange. For example, we face risks associated with regulatory approvals of offshore offerings, anti-monopoly regulatory actions, cybersecurity and data privacy, as well as the lack of inspection from the U.S. Public Company Accounting Oversight Board, or PCAOB, on our auditor. The PRC government may also intervene with or influence our operations as the government deems appropriate to further regulatory, political and societal goals. The PRC government has recently published new policies that significantly affected our industry and we cannot rule out the possibility that it will in the future further release regulations or policies regarding our industry that could adversely affect our business, financial condition and results of operations. Any such action, once taken by the PRC government, could cause the value of our securities to significantly decline or in extreme cases, become worthless.

Disaggregated Financial Information relating to the VIEs

In 2019, 2020 and 2021, external revenues contributed by the VIEs and their subsidiaries accounted for 100.0%, 100.0% and 99.98%, respectively, of our total revenues. As of December 31, 2020 and 2021, total assets of the VIEs, excluding amounts due from other companies in our group, equaled to 25.6% and 48.9% of our consolidated total assets as of the same dates, respectively.

Set forth below are the condensed consolidating schedule showing the financial position as of December 31, 2020 and 2021, and results of operations and cash flows for the years ended December 31, 2019, 2020 and 2021 for (i) Genetron Holdings Limited (the “Parent”); (ii) the PRC Subsidiaries, which are the primary beneficiaries of the VIEs; (iii) other subsidiaries (excluding the PRC Subsidiaries); (iv) the VIEs and their subsidiaries; (v) eliminating adjustments; and (vi) consolidated totals.

	As of December 31, 2020						As of December 31, 2021					
	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals
Condensed Consolidating Schedule of Financial Position												
Property, plant and equipment ⁽¹⁾	—	687	8,857	73,106	(5,759)	76,891	—	7,619	5,499	100,622	(3,455)	110,285
Right-of-use assets	—	—	—	59,706	—	59,706	—	11,091	730	40,245	—	52,074
Intangible assets	—	894	—	11,371	—	12,265	—	2,501	1,669	16,525	—	20,695
Financial assets at fair value through profit or loss	—	—	—	19,609	—	19,609	25,503	—	—	24,277	—	49,780
Prepayments	—	8,663	1,339	5,360	—	15,362	19,766	4,208	5,912	7,724	—	37,610
Amounts due from Group companies ⁽²⁾	—	759,105	732,010	—	(1,491,115)	—	—	1,360,431	1,168,130	—	(2,528,561)	—
Investments in subsidiaries and VIEs ⁽³⁾	728,152	—	—	—	(728,152)	—	1,138,922	—	210,000	—	(1,348,922)	—
Total non-current assets	728,152	769,349	742,206	169,152	(2,225,026)	183,833	1,184,191	1,385,850	1,391,948	189,393	(3,880,938)	270,444
Inventories ⁽¹⁾	—	—	—	26,120	(1,149)	24,971	—	—	477	35,700	(574)	35,603
Trade receivables	—	—	—	164,592	—	164,592	—	—	—	282,113	—	282,113
Other receivables and prepayments	12,116	4,976	1,603	23,725	—	42,420	7,170	2,037	16,455	72,233	—	97,895
Amounts due from Group companies ⁽²⁾	6,982	2,085	26,715	530	(36,312)	—	6,713	—	65,056	3,890	(75,659)	—
Amounts due from other related parties	—	—	—	—	—	—	—	—	—	597	—	597
Financial assets at fair value through profit or loss	31,953	—	29,109	79,232	—	140,294	91,562	—	9,824	49,957	—	151,443
Cash and cash equivalents	941,541	33,115	395,055	6,055	—	1,375,766	44,691	243,756	273,949	76,646	—	639,042
Other current assets	196	—	2,308	35,518	—	38,022	—	—	5,091	35,391	—	40,482
Total current assets	992,788	40,176	454,790	335,772	(37,461)	1,786,065	150,136	245,793	370,852	556,527	(76,233)	1,247,175
Total assets	1,720,940	809,525	1,196,996	504,924	(2,262,487)	1,969,898	1,334,327	1,631,643	1,762,900	745,920	(3,957,171)	1,517,619
Borrowings	—	—	—	5,493	—	5,493	—	—	—	—	—	—
Lease liabilities	—	—	—	43,016	—	43,016	—	9,587	—	24,278	—	33,865
Deficit in subsidiaries and VIEs ⁽³⁾	—	79,859	504,657	(584,516)	—	—	—	269,229	924,376	—	(1,193,605)	—
Amounts due to Group companies ⁽²⁾	—	—	759,105	732,010	(1,491,115)	—	75,457	—	1,074,974	1,378,130	(2,528,561)	—
Other non-current liabilities	—	—	—	—	—	—	—	—	8,612	—	—	8,612
Total non-current liabilities	—	79,859	1,263,762	780,519	(2,075,631)	48,509	75,457	278,816	2,007,962	1,402,408	(3,722,166)	42,477
Trade payables	—	284	8,736	28,051	—	34,071	—	—	8,016	47,751	—	55,767
Other payables and accruals	27,838	1,230	449	81,647	—	111,164	51,837	1,655	4,041	99,699	—	157,232
Amounts due to Group companies ⁽²⁾	533	—	—	35,779	(36,312)	—	1,442	—	2,448	71,680	(75,570)	19,554
Borrowings	—	—	—	58,583	—	58,583	—	—	—	19,554	—	78,137
Lease liabilities	—	—	—	16,585	—	16,585	—	2,161	711	17,700	—	20,572
Other current liabilities	24	—	—	8,417	—	8,441	—	—	461	11,504	—	11,965
Total current liabilities	28,395	1,514	6,185	229,062	(36,312)	228,844	53,279	3,816	15,677	267,888	(75,570)	265,090
Total liabilities	28,395	81,373	1,269,947	1,009,581	(2,111,943)	277,353	128,736	282,632	2,023,639	1,670,296	(3,797,736)	307,567
Total shareholders' equity/(deficit)	1,692,545	728,152	(72,951)	(504,657)	(150,544)	1,692,545	1,205,591	1,349,011	(260,739)	(924,376)	(163,896)	1,205,591
Non-controlling interests	—	—	—	—	—	—	—	—	—	—	4,461	4,461
Total equity and liabilities	1,720,940	809,525	1,196,996	504,924	(2,262,487)	1,969,898	1,334,327	1,631,643	1,762,900	745,920	(3,957,171)	1,517,619

Condensed Consolidating Schedule of Results of Operations	For the year ended December 31, 2019						For the year ended December 31, 2020						For the year ended December 31, 2021					
	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals
				(RMB in thousands)						(RMB in thousands)								(RMB in thousands)
Total revenue ⁽¹⁾	—	—	16,313	323,425	(16,313)	323,425	—	—	45,034	424,485	(45,034)	424,485	—	—	46,228	534,111	(46,228)	531,950
Total cost of revenue and expenses	(18,199)	(27)	(20,400)	(618,522)	16,698	(640,859)	(19,480)	(5,357)	(60,641)	(647,255)	46,189	(686,544)	(51,124)	(26,089)	(73,290)	(918,839)	51,267	(1,018,095)
Equity method on loss of subsidiaries ⁽²⁾	(416,121)	(418,391)	(406,239)	—	1,240,751	—	(225,796)	(258,868)	(236,102)	—	720,766	—	(445,020)	(445,998)	(425,411)	—	1,316,429	—
Financial instruments with preferred shares	(208,869)	—	—	(124,532)	—	(333,401)	(2,823,370)	—	—	—	—	(2,823,370)	—	—	—	—	—	—
Loss on fair value changes	(26,542)	—	—	—	—	(26,542)	—	—	—	—	—	—	—	—	—	—	—	—
Others-net	(6,303)	2,297	7	13,790	(8,448)	1,343	(397)	38,429	(8,314)	(13,332)	—	16,386	(94)	27,067	(2,763)	(40,663)	—	(16,453)
Loss before income tax	(676,034)	(416,121)	(410,328)	(406,239)	1,232,688	(676,034)	(3,069,043)	(225,796)	(260,023)	(236,102)	721,921	(3,069,043)	(496,238)	(445,020)	(455,236)	(425,411)	1,319,387	(582,598)
Income tax expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Loss for the year	(676,034)	(416,121)	(410,328)	(406,239)	1,232,688	(676,034)	(3,069,043)	(225,796)	(260,023)	(236,102)	721,921	(3,069,043)	(496,238)	(445,020)	(455,236)	(425,411)	1,319,387	(582,598)
Owners of the Company	(676,034)	(416,121)	(410,328)	(406,239)	1,232,688	(676,034)	(3,069,043)	(225,796)	(260,023)	(236,102)	721,921	(3,069,043)	(496,238)	(445,020)	(455,236)	(425,411)	1,325,667	(496,238)
Non-controlling interests	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(6,300)	(6,300)

Condensed Consolidating Schedule of Cash Flows	For the year ended December 31, 2019						For the year ended December 31, 2020						For the year ended December 31, 2021					
	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals	Parent	Other Subsidiaries	PRC Subsidiaries	VIEs and their subsidiaries	Eliminating Adjustments	Consolidated Totals
	(RMB in thousands)						(RMB in thousands)						(RMB in thousands)					
Net cash (used in)/generated from operating activities	(10,805)	(26)	5,942	(192,068)	—	(196,957)	(36,241)	(12,459)	(55,603)	(196,594)	—	(300,897)	(35,706)	(18,256)	(64,272)	(405,910)	—	(524,144)
Investment in subsidiaries ⁽³⁾	(231,062)	(21,159)	—	—	252,221	—	(1,006,010)	(438,036)	—	—	1,444,046	—	(886,610)	(258,607)	(210,000)	—	1,355,217	—
Loans to Group companies ⁽⁴⁾	—	(212,200)	(232,586)	—	444,786	—	—	(546,384)	(499,424)	—	1,045,808	—	—	(1,371,357)	(718,600)	—	2,089,957	—
Repayments of loans from Group companies ⁽⁴⁾	—	—	—	—	—	—	—	—	—	—	—	—	—	770,000	282,480	—	(1,052,480)	—
Other investing activities	—	—	—	(96,807)	—	(96,807)	(34,323)	(9,489)	(31,614)	(9,223)	—	(84,649)	(91,931)	(5,154)	13,509	(52,699)	—	(136,275)
Net cash (used in)/ generated from investing activities	(231,062)	(233,359)	(232,586)	(96,807)	697,007	(96,807)	(1,040,333)	(993,909)	(531,038)	(9,223)	2,489,854	(84,649)	(978,541)	(865,118)	(632,611)	(52,699)	2,392,694	(136,275)
Capital contribution from Group companies ⁽⁵⁾	—	231,062	21,159	—	(252,221)	—	—	1,006,010	438,036	—	(1,444,046)	—	—	1,096,610	258,607	—	(1,355,217)	—
Proceeds from loans from Group companies ⁽⁴⁾	—	—	212,200	232,586	(444,786)	—	—	546,384	499,424	(1,045,808)	—	75,457	—	—	1,085,900	928,600	(2,089,957)	—
Repayments of loans from Group companies ⁽⁵⁾	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(770,000)	(282,480)	1,052,480	—
Proceeds from issuance of ordinary shares and financial instruments with preferred rights	456,586	—	—	—	—	456,586	1,746,842	—	—	—	—	1,746,842	—	—	—	—	—	—
Repurchase of ordinary shares and financial instruments with preferred rights	(97,758)	—	—	—	—	(97,758)	(4,102)	—	—	—	(4,102)	—	—	—	—	—	—	—
Other financing activities	7,616	—	(188)	5,475	—	12,903	300,429	—	—	(298,657)	—	1,772	50,786	(1,277)	8,936	(116,830)	—	(58,405)
Net cash generated from / (used in) financing activities	366,444	231,062	233,171	238,061	(697,007)	371,731	2,043,169	1,006,010	984,420	200,767	(2,489,854)	1,744,512	126,243	1,095,333	583,443	529,270	(2,392,694)	(58,405)
Net increase/(decrease) in cash and cash equivalents	124,577	(2,323)	6,527	(50,814)	—	77,967	966,595	(358)	397,779	(5,050)	—	1,358,966	(888,004)	211,959	(113,440)	70,661	—	(718,824)
Exchange differences on cash and cash equivalents	(2,473)	2,390	(38)	(18)	—	(139)	(147,158)	33,406	(9,213)	(189)	—	(123,154)	(8,846)	(1,318)	(7,666)	(70)	—	(17,900)
Cash and cash equivalents at beginning of year	—	—	—	62,126	—	62,126	122,104	67	6,489	11,294	—	139,954	941,541	33,115	395,055	6,055	—	1,375,766
Cash and cash equivalents at end of year	122,104	67	6,489	11,294	—	139,954	941,541	33,115	395,055	6,055	—	1,375,766	44,691	243,756	273,949	76,646	—	639,042

Notes:

- (1) It includes intercompany sales of equipment and reagents, among others, between PRC Subsidiaries and VIEs and their subsidiaries, which were eliminated at the consolidation level. For the years ended December 31, 2019, 2020 and 2021, the PRC Subsidiaries did not charge any service fees from VIEs and their subsidiaries.
- (2) It represents the intercompany balances eliminated at the consolidation level.
- (3) It represents the elimination of the investment in PRC Subsidiaries and other subsidiaries at the consolidation level.
- (4) It represents the elimination of the intercompany advances and repayments among companies within our group.

Transfer of Funds and Other Assets

Under PRC law, Genetron Holdings Limited may provide funding to our PRC Subsidiaries only through capital contributions or loans, and to the VIEs only through loans, subject to satisfaction of applicable government registration and approval requirements.

In 2019, 2020 and 2021, PRC Subsidiaries and other subsidiaries made loans in total of RMB232.6 million, RMB499.4 million and RMB928.6 million (US\$145.7 million) to the VIEs, respectively. As of December 31, 2020 and 2021, there were RMB732.0 million and RMB1,378.1 million (US\$216.3 million) outstanding under such loans.

As of December 31, 2021, Genetron Holdings Limited made cumulative capital contributions of RMB620.0 million (US\$97.3 million) to Genetron (Tianjin) Co., Ltd. and RMB97.9 million (US\$15.4 million) to Genetron (Wuxi) Business Management Co., Ltd. through intermediate holding company, and these were accounted as long-term investments of Genetron Holdings Limited. These funds have been used by subsidiaries of the VIEs for their operations.

Our PRC Subsidiaries, maintained certain personnel to support the operations of the VIEs. There were no other assets transferred between the VIEs and other entities in 2019, 2020 and 2021.

Genetron Holdings Limited has not previously declared or paid any cash dividend or dividend in kind, and has no plan to declare or pay any dividends in the near future on our shares or the ADSs representing our ordinary shares. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business. See “Item 8. Financial Information—8.A. Consolidated Statements and Other Financial Information—Dividend Policy.”

For the purpose of illustration, the below table reflects the hypothetical taxes that might be required to be paid within China, assuming that (i) we have taxable earnings and (ii) we determine to pay a dividend in the future:

Taxation Scenario ⁽¹⁾	
Statutory Tax and Standard Rates	
Hypothetical pre-tax earnings ⁽²⁾	100 %
Tax on earnings at statutory rate of 25% ⁽³⁾	(25)%
Net earnings available for distribution	75 %
Withholding tax at standard rate of 10% ⁽⁴⁾	(7.5)%
Net distribution to Parent/Shareholders	67.5 %

Notes:

(1) For purposes of this hypothetical example, the tax calculation has been simplified. The hypothetical book pre-tax earnings amount, not considering timing differences, is assumed to equal Chinese taxable income.

(2) Under the terms of VIE agreements, our PRC Subsidiaries may charge the VIEs for services provided to VIEs. These fees shall be recognized as expenses of the VIEs, with a corresponding amount as service income by our PRC Subsidiaries and eliminated in consolidation. For income tax purposes, our PRC Subsidiaries and VIEs file income tax returns on a separate company basis. The fees paid are recognized as a tax deduction by the VIEs and as income by our PRC Subsidiaries and are tax neutral.

(3) Certain of our subsidiaries and VIEs qualifies for a 15% preferential income tax rate in China. However, such rate is subject to qualification, is temporary in nature, and may not be available in a future period when distributions are paid. For purposes of this hypothetical example, the table above reflects a maximum tax scenario under which the full statutory rate would be effective.

(4) China's Enterprise Income Tax Law imposes a withholding income tax of 10% on dividends distributed by a Foreign Invested Enterprises (“FIE”) to its immediate holding company outside of China. A lower withholding income tax rate of 5% will be applied if the FIE's immediate holding company is registered in Hong Kong or other jurisdictions that have a tax treaty arrangement with China, subject to a qualification review at the time of the distribution. For purposes of this hypothetical example, the table above assumes a maximum tax scenario under which the full withholding tax would be applied.

The table above has been prepared under the assumption that all profits of the VIEs will be distributed as fees to our PRC Subsidiaries under tax neutral contractual arrangements. If in the future, the accumulated earnings of the VIEs exceed the fees paid to our PRC Subsidiaries, or if the current and contemplated fee structure between the intercompany entities is determined to be non-substantive and disallowed by Chinese tax authorities, we have other tax-planning strategies that can be deployed on a tax neutral basis.

Should all tax planning strategies fail, the VIEs could, as a matter of last resort, make a non-deductible transfer to our PRC Subsidiaries for the amounts of the stranded cash in the VIEs. This would result in the double taxation of earnings: one at the VIEs level (for non-deductible expenses) and one at the PRC Subsidiaries level (for presumptive earnings on the transfer). Such a transfer and the related tax burdens would increase our after-tax loss to approximately 50.6% of the pre-tax loss. Our management is of the view that the likelihood that this scenario would happen is remote.

Restrictions on Foreign Exchange and the Ability to Transfer Cash between Entities, Across Borders and to U.S. Investors

Genetron Holdings Limited's ability to pay dividends, if any, to its shareholders and ADS holders and to service any debt it may incur will depend upon dividends paid by our PRC Subsidiaries. Under PRC laws and regulations, our PRC Subsidiaries are subject to certain restrictions with respect to paying dividends or otherwise transferring any of their net assets offshore to Genetron Holdings Limited. In particular, under the current effective PRC laws and regulations, dividends may be paid only out of distributable profits. Distributable profits are the net profit as determined under PRC GAAP, less any recovery of accumulated losses and appropriations to statutory and other reserves required to be made. Each of our PRC Subsidiaries is required to set aside at least 10% of its after-tax profits each year, after making up previous years' accumulated losses, if any, to fund certain statutory reserve funds, until the aggregate amount of such a fund reaches 50% of its registered capital. As a result, our PRC Subsidiaries may not have sufficient distributable profits to pay dividends to us in the near future.

Furthermore, if certain procedural requirements are satisfied, the payment of current account items, including profit distributions and trade and service related foreign exchange transactions, can be made in foreign currencies without prior approval from State Administration of Foreign Exchange ("SAFE") or its local branches. However, 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, approval from or registration with competent government authorities or its authorized banks is required. The PRC government may take measures at its discretion from time to time to restrict access to foreign currencies for current account or capital account transactions. 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 offshore intermediary holding companies or ultimate parent company, and therefore, our shareholders or investors in our ADSs. Further, we cannot assure you that new regulations or policies will not be promulgated in the future, which may further restrict the remittance of RMB into or out of the PRC. We cannot assure you, in light of the restrictions in place, or any amendment to be made from time to time, that our current or future PRC subsidiaries will be able to satisfy their respective payment obligations that are denominated in foreign currencies, including the remittance of dividends outside of the PRC. If any of our subsidiaries incurs debt on its own behalf in the future, the instruments governing such debt may restrict its ability to pay dividends to Genetron Holdings Limited. In addition, our PRC Subsidiaries are required to make appropriations to certain statutory reserve funds, which are not distributable as cash dividends except in the event of a solvent liquidation of the companies.

For PRC and United States federal income tax consideration of an investment in the ADSs, see "Item 10. Additional Information—10.E. Taxation."

Permissions Required from the PRC Authorities for Our Operations

We conduct our business primarily through our PRC subsidiaries, the VIEs, and subsidiaries of the VIEs in China. Our operations in China are governed by PRC laws and regulations. As of the date of this annual report, the VIEs and subsidiaries of the VIEs in China have obtained the requisite licenses and permits from the PRC government authorities that are material for the business operations of our holding company, our PRC subsidiaries, the VIEs and subsidiaries of the VIEs in China. See “Item 5. Operating and Financial Review and Prospects—5.C. Research and Development, Patents and Licenses, Etc.” However, given the uncertainties of interpretation and implementation of relevant laws and regulations and the enforcement practice by government authorities, we cannot assure you that we have obtained all the permits or licenses required for conducting our business in China. For example, despite the rapid development of LDTs in China in recent years, due to the relatively short history of the LDT industry in China, a comprehensive regulatory framework governing the LDT industry has not been established. There are certain risks associated with the regulatory uncertainties of the provision of our LDT services in China. For details of such risks and regulatory uncertainties, see “Item 3. Key Information—3.D. Risk Factor—Risks Related to Our Business and Industry—We may be adversely affected by the uncertainties and changes in the regulation of cancer genomic testing service industry or LDT industry in general in the PRC, and any lack of requisite approvals, permits, registrations or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects, and “Item 3. Key Information—3.D. Risk Factor—Risks Related to Our Business and Industry—If we fail to obtain applicable licenses or registrations for our IVD medical products, we will be unable to commercially manufacture, distribute and market our products, and our commercialization of IVD medical products might be substantially harmed.”

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. Reserved

3.B. Capitalization and Indebtedness

Not applicable.

3.C. Reason for the Offer and Use of Proceeds

Not applicable.

3.D. Risk Factors

You should carefully consider all of the information in this annual report before making an investment in the ADSs. Below please find a summary of the principal risks and uncertainties we face, organized under relevant headings. In particular, as we are a China-based company incorporated in the Cayman Islands, you should pay special attention to subsections headed “Item 3. Key Information—3.D. Risk Factors—Risks Related to Doing Business in China” and “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Corporate Structure.”

Risks Related to Doing Business in China

We are a China-based company and we may face risks and uncertainties in doing business in China, including:

- Uncertainties with respect to the PRC legal system, including uncertainties regarding the enforcement of laws, and changes in laws, regulations and policies in China could adversely affect us.
- The PCAOB is currently unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections over our auditor deprives our investors with the benefits of such inspections;
- Trading in our ADSs on the Nasdaq Stock Market or in the over-the-counter market will be prohibited, and as a result, our ADSs will be delisted under the HFCA Act, if the PCAOB is unable to inspect or fully investigate auditors located in China. On December 16, 2021, the PCAOB issued the HFCA Act Determination Report, according to which our auditor is subject to the determinations that the PCAOB is unable to inspect or investigate completely. The delisting of our ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment. If this happens there is no certainty that we will be able to list our ordinary shares on a non-U.S. exchange or that a market for our ordinary shares will develop outside of the United States;
- The potential enactment of the Accelerating Holding Foreign Companies Accountable Act would decrease the number of non-inspection years from three years to two, thus reducing the time period before our ADSs may be prohibited from trading on the Nasdaq Stock Market or in the over-the-counter market or delisted;

- PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may restrict or delay us from using the proceeds of our financing activities to make loans or additional capital contributions to our PRC subsidiaries and making loans to the VIE or its subsidiaries, which could adversely affect our liquidity and our ability to fund and expand our business; and
- Proceedings instituted by the SEC against four PRC-based accounting firms, including our independent registered public accounting firm, could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act.

Risks Related to Our Corporate Structure

We face risks and uncertainties related to our corporate structure, including:

- There are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations, and rules relating to the agreements that establish the VIE structure for our operations in China, including potential future actions by the PRC government, which could affect the enforceability of our contractual arrangements with the VIE and, consequently, significantly affect the financial condition and results of operations. If the PRC government finds such agreements non-compliant with relevant PRC laws, regulations, and rules, or if these laws, regulations, and rules or the interpretation thereof change in the future, we could be subject to severe penalties or be forced to relinquish our interests in the VIE.
- Any failure by the VIEs or their shareholders to perform their obligations under our contractual arrangements with them would have a material adverse effect on our business.
- We may be required to obtain approval or complete filing or other requirements of the CSRC or other PRC government authorities in connection with our issuances of securities overseas, and, if required, we cannot predict whether we will be able to obtain such approval or complete such governmental procedure.
- Substantial uncertainties exist with respect to the interpretation and implementation of the Foreign Investment Law of the PRC and how it may impact the viability of our current corporate structure, corporate governance and business operations.
- We rely on contractual arrangements with the VIEs and their shareholders for our business operations, which may not be as effective as direct ownership in providing operational control.

Risks Related to Our Limited Operating History, Our Financial Prospectus and Need for Additional Capital

We face risks and uncertainties with respect to our limited operating history, our financial prospectus and need for additional capital, including:

- We have incurred net losses historically and we may continue to incur net losses in the near future.
- We recorded negative cash flows from operating activities historically and may have a net current liabilities position in the future.
- Our need to obtain substantial additional financing to fund our growth and operations.
- As of the date of this annual report, our revenue was primarily generated from diagnosis and monitoring services and products and we are highly dependent on it for our success.

Risks Related to Our Business and Industry

We face risks and uncertainties related to our business and industry, including:

- Our business and financial prospects depend substantially upon obtaining regulatory approval and the successful commercialization of our services and products in the future, which may fail or experience significant delays.
- We may be adversely affected by the uncertainties and changes in the regulation of cancer genomic testing service industry or LDT industry in general in the PRC, and any lack of requisite approvals, permits, registrations or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects.
- Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, investigation or sanction by regulatory authorities, private litigation, other liabilities, and/or adverse publicity. Non-compliance or failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.
- Even though we have received breakthrough device designation for our HCCscreen™ for hepatocellular carcinoma, this designation may not expedite the development or review of HCCscreen™ and does not provide assurance ultimately of premarket approval submission or approval by the FDA.
- If we fail to comply with United States federal and state healthcare laws and regulations in connection with our activities in the United States, we could face substantial penalties and our business, operations and financial condition could be adversely affected.
- We may face intense competition and our competitors may develop similar, but more advanced services and products than ours, which may adversely affect our business and financial conditions.

Risks Related to Our Operations

We face risks and uncertainties in realizing our business objectives and executing our strategies, including:

- If we are unable to support demand for our existing or future precision oncology services and products, including ensuring that we have adequate capacity to meet increased demand, our business could suffer.
- We may pursue collaborations, in-licensing or out-license arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements, which may fail to produce anticipated benefits and adversely affect our operations.
- Our business depends on a strong brand, and failing to maintain and enhance our brand would adversely affect our business, results of operations and financial condition.
- Our business, financial condition and results of operations, as well as our ability to obtain financing, may be adversely affected by a downturn in the global or China's economy.

Risks Related to Our Intellectual Property

We face risks and uncertainties related to our intellectual property, including:

- We may be unsuccessful in obtaining or maintaining adequate intellectual property protection for one or more of our services and products, and our patents could be found invalid or unenforceable if challenged in court or before administrative bodies.
- Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Patent terms may not be sufficient to effectively protect our services and products and business.

Risks Related to the American Depositary Shares

In addition to the risks described above, we are subject to risks related to our ordinary shares and our ADSs, including, but are not limited to, the following:

- Our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ADSs, may be adversely affected by the geopolitical factors arising in connection with the military operations of Russia in Ukraine, including particularly how countries like the United States and China choose to respond to this ongoing military conflict. As a result, the value of our ADSs may significantly decline.
- The trading price of the ADSs is likely to be volatile, which could result in substantial losses to investors.
- Litigation and negative publicity surrounding China-based companies listed in the U.S. may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs and could have a material adverse effect upon our business, results of operations, financial condition and prospects.
- The voting rights of holders of ADSs are limited by the terms of the deposit agreement, and you may not be able to exercise your right to vote the underlying ordinary shares represented by your ADSs.
- Techniques employed by short sellers may drive down the trading price of the ADSs.
- We cannot assure you that the ADSs will remain listed on Nasdaq.
- Although we believe we were not a passive foreign investment company for 2021, due to our ADSs' price fluctuations there is a significant risk that we will be a passive foreign investment company for 2022 or any future taxable year, which could result in adverse U.S. federal income tax consequences to U.S. investors in the ADSs or our ordinary shares.

RISKS RELATED TO OUR LIMITED OPERATING HISTORY, OUR FINANCIAL PROSPECTS AND NEED FOR ADDITIONAL CAPITAL

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We commenced our operation in 2015 through Genetron Health. Since then, we have achieved rapid growth and continue to expand our services and products. Our operations are focused on diagnosis and monitoring, early screening, and development services. Our limited operating history may make it difficult to evaluate our current business and predict our future performance. Any predictions you make about our future success or viability may be subject to uncertainty and may not be as accurate as they could be if we had a longer operating history. We may encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transit to a company capable of supporting commercial activities. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business, financial condition and results of operations may be adversely affected.

We have incurred net losses historically and we may continue to incur net losses in the near future.

We have incurred losses since our inception. For the years ended December 31, 2019, 2020 and 2021, we incurred net losses of RMB676.0 million, RMB3,069.0 million and RMB502.6 million (US\$78.9 million), respectively. To date, we have financed our operations principally from capital contributions from our shareholders and proceeds from our initial public offering on Nasdaq. We have devoted substantial resources to the research and development and commercialization of our diagnosis services and products, and plan to substantially invest in the research and development related to our cancer early screening business and seeking regulatory approvals with respect to our IVD products, including preclinical studies, clinical and regulatory initiatives to obtain relevant marketing approvals and sales and marketing activities. We are also in various stages of research and development for other services and products that we may offer. We will need to generate significant additional revenue to achieve profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time. Our failure to achieve profitability would negatively affect our business, financial condition, results of operations, and cash flows. If we are unable to execute our sales and marketing strategy for our services and products and are unable to gain sufficient acceptance in the market, we may be unable to generate sufficient revenues to sustain our business.

We recorded negative cash flows from operating activities historically and may have a net current liabilities position in the future.

We have experienced significant cash outflow from operating activities since our inception. We had net cash used in operating activities of RMB197.0 million, RMB300.9 million and RMB524.1 million (US\$82.3 million) for the years ended December 31, 2019, 2020 and 2021, respectively. The cost of continuing operations could further reduce our cash position, and an increase in our net cash outflow from operating activities could adversely affect our operations by reducing the amount of cash available to meet the cash needs for operating our business and to fund our investments in our business expansion.

Although we had net current assets of RMB982.1 million (US\$154.1 million) as of December 31, 2021, we cannot guarantee that we will not have a net current liabilities position in the future, which would expose us to liquidity risk. Our future liquidity and ability to make additional capital investments necessary for our operations and business expansion will depend primarily on our ability to generate and maintain sufficient cash inflow from operating activities and to obtain adequate external financing. There can be no assurance that we will be able to renew existing bank facilities or obtain other sources of financing.

The COVID-19 outbreak has brought uncertainties and interruptions to the global economy and caused significant volatility across the financial markets, which had a cooling effect on financing and investing activities in general. Based on our current business plan, we believe that our current cash and cash equivalents, together with our cash generated from financing activities, including proceeds from our initial public offering on Nasdaq and pre-IPO private placements, will be sufficient to meet our currently anticipated working capital requirements and capital expenditures for at least the next 12 months. However, if the impact of COVID-19 and volatility in the financial markets continue, our financing activities in future to raise additional capital may be materially and adversely affected, which may in turn have an adverse effect on our ability to meet our working capital requirements and our liquidity. For other risks related to COVID-19, see “—Risks Related to our Operations—We face risks related to health epidemics, including COVID-19, severe weather conditions and other outbreaks.”

We may need to obtain substantial additional financing to fund our growth and operations.

We will need to expend substantial resources for research and development and commercialization of our services and products candidates, including costs associated with:

- clinical trials for our services and products candidates at discovery and pre-commercialization stage;
- research and development on additional services and products; and
- commercialization of our services and products.

To date, we have funded our operations primarily through capital contributions from our shareholders and proceeds from our initial public offering on Nasdaq. In addition, we received government grants of RMB11.7 million, RMB3.9 million and RMB4.0 million (US\$0.6 million) in 2019, 2020 and 2021, respectively. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was RMB197.0 million, RMB300.9 million and RMB524.1 million (US\$82.3 million) for the years ended December 31, 2019, 2020 and 2021, respectively. We had cash and cash equivalents of RMB1,375.8 million and RMB639.0 million (US\$100.3 million) as of December 31, 2020 and 2021, respectively. We expect our expenses to increase significantly in connection with our ongoing operations, particularly as we advance the development of our proprietary technologies and invest in the commercialization of our full-cycle cancer management products. In addition, we require significant capital to build, maintain, operate and expand our laboratory facilities and engage in research and development activities. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on commercially acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts.

Raising additional capital may lead to a dilution of shareholdings by our existing shareholders and restrict our operations.

We may seek additional funding through a combination of equity and debt financings, collaborations or licensing arrangements or other sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing holders of our shares and/or ADS investors will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing shareholders and/or ADS holders.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license IP rights and other operating restrictions that could adversely impact our ability to conduct our business.

As of the date of this annual report, our revenue was primarily generated from diagnosis and monitoring services and products and we are highly dependent on it for our success.

As of the date of this annual report, our revenue was primarily generated from diagnosis and monitoring services and products. We expect that the revenue of our diagnosis and monitoring services and products business will continue to account for a substantial portion of our revenues going forward. Our ability to generate profits will therefore largely depend upon the acceptance and adoption of our diagnosis and monitoring services and products by our customers. The increase in acceptance and adoption of these services and products will depend on numerous factors, including the prices we charge for our tests, the broader coverage of our LDT services and IVD products, the availability of clinical data that supports the value of our diagnosis and monitoring services and products and the recognition of these services and products by hospitals, doctors, KOLs and others in the medical community. We cannot assure you that our diagnosis and monitoring services and products will continue to maintain or gain market acceptance, and any failure to do so would harm our business and results of operations.

We may face certain risks in collecting our receivables, and the failure to collect could adversely affect our business, financial condition and results of operations.

As of December 31, 2020 and 2021, our trade receivables, other receivables and prepayments and contract assets were, in aggregate, RMB208.1 million and RMB387.8 million (US\$60.9 million), respectively, and the loss allowance for trade and other receivables and contract assets was RMB18.9 million and RMB55.2 million (US\$8.7 million), respectively. As our business continues to scale, our trade and other receivables and contract assets balance may continue to grow, which may increase our risks for uncollectible receivables. Actual losses on receivables balance could differ from those that we anticipate and reserve in our allowance for doubtful accounts, as a result we might need to adjust our allowance. Macroeconomic conditions could also result in financial difficulties for our customers, including limited access to the credit markets, insolvency or bankruptcy, and as a result could cause customers to delay payments to us, request modifications to their payment arrangements or default on their payment obligations to us. If we are unable to collect our trade and other receivables and contract assets from our customers, our business, financial condition and results of operation may be materially and adversely affected.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

Our business and financial prospects depend substantially upon obtaining regulatory approval and the successful commercialization of our services and products in the future, which may fail or experience significant delays.

Although we have developed and marketed several diagnosis and monitoring services and products to date, we believe our future success is dependent upon our ability to continuously develop technologies and successfully market our existing cancer genetic offerings to customers within the PRC and expand into overseas markets. Our ability to generate significant revenue in the next several years will depend primarily on the successes of each key stage of our business, including pre-clinical research and development, clinical trial, regulatory approval, manufacturing, marketing and commercialization of our services and products, each of which is subject to significant uncertainty. Our IVD pipeline products are in various stages of development. It may take several more years for us to develop them and they may be required to undergo extensive clinical validation. Our ability to generate sales revenue from our products and services and our future profitability depends on a number of factors, including our ability to continue:

- obtaining regulatory approvals and marketing authorizations for our services and products;
- obtaining market acceptance by patients, hospitals, clinicians, KOLs, biopharmaceutical companies and others in the medical community;
- establishing sufficient testing capacity and commercial manufacturing capabilities, either by expanding our current facility or making arrangements with third parties;
- developing and maintaining our sales network to launch and commercialize our new cancer genomic testing services and products;
- setting appropriate and favorable prices for our cancer genomic testing services and products and obtaining coverage and adequate reimbursement;
- maintaining commercially viable supply relationships with third parties and maintaining sufficient research and development capabilities and infrastructure;
- addressing any competing technological and market developments; and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how.

If we do not achieve one or more of these milestones in a timely manner or at all, we could experience significant delays in our ability to obtain approvals for our services and products or to successfully commercialize our services and products, any of which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Our ability to become profitable in the future will depend on various factors, including the market acceptance of our services and products.

We are a growing precision oncology company and have engaged in targeted sales and marketing activities for our services and products. Our services and products are relatively innovative and may never gain significant acceptance in the marketplace or generate substantial revenue or permit us to become profitable. We will need to further expand our products and services offerings through research and development efforts and the expansion of our current relationships and development of new relationships with hospitals, KOLs and biopharmaceutical companies. Our ability to achieve and maintain commercial market acceptance of our existing and future services and products will depend on a number of factors, including:

- our ability to demonstrate the utility and value of our full-cycle cancer clinical treatment to our customers;
- our ability to promote the awareness of our services and products;

- the rate of adoption and/or endorsement of our tests by clinicians, KOLs, and biopharmaceutical companies;
- the timing and scope of the relevant regulatory approvals for our services and products;
- whether our services and products are considered superior to those of our competitors;
- absence of negative publicity regarding our or our competitors' products resulting from defects or errors; and
- our ability to further validate our technology through clinical research and accompanying publications.

We cannot assure you that we will be successful in addressing each of these criteria or other criteria that may affect the market acceptance of our services and products. Failure to achieve broad market acceptance of our services would materially harm our business, financial condition, and results of operations.

We may be adversely affected by the uncertainties and changes in the regulation of cancer genomic testing service industry or LDT industry in general in the PRC, and any lack of requisite approvals, permits, registrations or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects.

Due to the relatively short history of the cancer genomic testing service industry or LDT industry in general in the PRC, a comprehensive regulatory framework governing our industry has not been established. We cannot rule out the possibility that some common practices in our industry which we also adopt might be viewed as not being in full compliance with the existing PRC laws and regulations.

According to the Administration Measures for Clinical Gene Amplification Test Laboratories of Medical Institutions, promulgated by the Ministry of Health (a predecessor of NHC) and effective from December 6, 2010, a clinical gene amplification testing laboratory is prohibited from conducting any clinical amplification testing items that have not been registered with the relevant health administrative authority in accordance with the Catalogue of Clinical Laboratory Items for Medical Institutions (2013) (the "Testing Items Catalogue"). As of the date of this annual report, many of our LDT testing items have not been included in the Testing Items Catalogue". As a result, we are not able to register or file such testing items with the applicable PRC health administrative authority.

In February 2016, the NHFPC, a predecessor of NHC, issued the Notice on Issues Related to the Management of Clinical Laboratory Items ("Circular 167"), pursuant to which medical institutions are required to establish and improve the management of clinical laboratory items, and clinical testing items that are not included in the Testing Items Catalogue but are with clear clinical significance, relatively high specificity and sensitivity, and reasonable price, should be validated in time to meet clinical needs. However, the notions of "clear clinical significance," "relatively high specificity and sensitivity," and "reasonable price" are not defined by the Circular 167. As advised by Shihui Partners, our PRC legal counsel, in practice, although there is currently no clear regulatory guidance on these notions, testing items outsourced by a hospital in the PRC are generally deemed to be of "clear clinical significance," "relatively high specificity and sensitivity," and "validated in time to meet clinical needs." Based on the view of Shihui Partners, our PRC legal counsel, we believe that our LDT tests are of "clear clinical significance" and "relatively high specificity and sensitivity." In addition, we believe testing items outsourced by a public hospital in the PRC are generally considered as reasonably priced. In this connection, we also had consultations with the competent government authorities between April and August 2021 ("Government Consultations"). Based on the Government Consultations and as advised by Shihui Partners, our PRC legal counsel, we believe that the possibility of us being subject to any administrative penalties for conducting LDT tests beyond the scope of the Testing Items Catalogue is relatively low, and that pursuant to the Circular 167, we can continue to conduct clinical testing of such items not included in the Testing Items Catalogue as long as they have clear clinical significance, relatively high specificity and sensitivity, and reasonable price. We will closely monitor and assess any regulatory development in this regard. If the PRC government promulgates clear regulatory guidelines or interpretations on Circular 167, we intend to take necessary measures to comply with applicable requirements. Any failure to meet existing and future requirements may prevent us from conducting our testing items and adversely affect our business operation.

In February 2014, the General Office of NHFPC and the General Office of CFDA (a predecessor of the NMPA) jointly issued the Notice of Strengthening the Administration of Products and Technologies Related to Clinical Genomic Testing ("Notice No. 25"). Pursuant to Notice No. 25, pilot enterprises designated by the NHFPC, the regulator over the clinical use of genomic testing technology, may use genomic testing technologies and products on trial, and medical institutions are prohibited from the clinical use of any genomic testing technologies or products before the promulgation of relevant regulations. In March 2014, the Medical Affairs and Hospital Administration Bureau of the NHFPC issued a notice to launch the pilot scheme on the clinical use of NGS.

Based on the Governmental Consultations, the first group of pilot enterprises in the field of cancer genomic testing are mainly hospitals, and we have also been informed that no other enterprises have been so designated, and no implementing rules in relation to NGS-based test have been promulgated. However, as informed by the government authority, clinical laboratories conducting cancer genomic testing with a good operation record, including those of our Company, are allowed to continue providing LDT-based cancer genomic testing, without obtaining any special license or being designated as a pilot enterprise, before any relevant final regulations are promulgated. Our PRC legal counsel, Shihui Partners, taking into consideration of the Government Consultations, further advised us that our application of NGS technology in the provision of LDT services is in compliance with the current PRC laws and regulations in all material aspects. If the PRC government promulgates detailed requirements for the application of NGS technology in the future, we intend to take necessary measures to meet such requirements.

Additionally, pursuant to Notice No. 25, genomic testing diagnostic products, including gene sequencing platforms and relevant diagnostic assays or software, will be deemed as medical devices and regulated under the then effective Regulations on the Supervision and Administration of Medical Devices, and therefore genomic testing diagnostic products used in cancer genomic testing services, such as ours, are required to be registered with the NMPA or its local counterparts. Any failure to do so may result in fines, confiscation of involved products, and/or business suspension. In February 2021, the State Council promulgated the amended Regulations on the Supervision and Administration of Medical Device ("2021 Medical Devices Regulations"), which became effective from June 1, 2021. Pursuant to the 2021 Medical Devices Regulations, with respect to *in vitro* reagents, if no product of the same kind has been approved for marketing in China, qualified medical institutions may, according to their clinical needs, develop these *in vitro* reagents in-house for their own use under the guidance of practicing physicians. The NMPA and the NHC are authorized to jointly promulgate more detailed regulations related to such provision.

No NGS-based cancer genomic testing assay had been registered with NMPA in association with genomic sequencing platforms until a 4-gene assay was registered with NMPA in July 2018. Although there had been a few cancer genomic sequencing platforms and assays registered with NMPA in cancer genomic testing industry, we believe these registered cancer genomic sequencing platforms and assays may not satisfy the demand for comprehensive and high-throughput testing in the field of cancer genomic testing. We believe the adoption of cancer genomic testing service is often time-sensitive in practice, while the NMPA registration pathway for cancer genomic testing diagnostic products is constantly evolving, which may lead to an uncertain and lengthy registration process. In light of these, we believe cancer genomic testing laboratories, including ours, are commonly seen in the industry to use unregistered cancer genomic testing diagnostic products when providing cancer genomic testing services.

Based on the Governmental Consultations, we have been informed that (i) clinical laboratories conducting cancer genomic testing with a good operation record, including those of our Company, are allowed to continue providing LDT-based cancer genomic testing, without obtaining any special registration approval or perform any record-filing of products, such as testing reagents, used in such services, and (ii) clinical laboratories, including those of our Company, are allowed to continue providing LDT-based cancer genomic testing with unregistered testing reagents for research, clinical development and commercial use. Our PRC legal counsel, Shihui Partners, taking into consideration the Governmental Consultations, further advised us that our Company is permitted to continue to provide Genomic LDTs with unregistered testing reagents. If the PRC government promulgates detailed requirements for the registration or approval of genomic testing diagnostic products used in cancer genomic testing services, or any interpretation or implementing rules with respect to the regulations over *in vitro* reagents under the 2021 Medical Devices Regulations, in the future, we intend to take necessary measures to meet such requirements.

As of the date of this annual report, we had obtained comprehensive panel accreditation under the CLIA from the Centers for Medicare & Medicaid Services (“CMS”), a certification from the College of American Pathologists (“CAP”) and ISO 15189 certificate issued by American Association For Laboratory Accreditation, being one of the few NGS laboratories in China that have all three international accreditations. Our Beijing clinical laboratory also received full marks under the NCCL’s first nationwide EQA of NGS-based comprehensive genomic profiling for solid tumors in August 2021, earning the designation “Outstanding Laboratory” and ranking first among all of the 63 laboratories that participated in the evaluation. Our Guangzhou lab is officially approved to offer Onco PanScan™ in December 2021, which was previously approved for pilot run by the Guangdong Bureau of the NCCL. As of the date of this annual report, we had not been subject to any material fines or other penalties related to our practices described above. However, we cannot rule out the possibility that regulatory agencies in China may change their enforcement practices, and therefore, prior enforcement activity, or lack of enforcement activity, is not necessarily predictive of future actions. The regulatory framework for this industry is also evolving and may remain uncertain for the foreseeable future. If the PRC government promulgates new requirement for the application of NGS technology, or products, including sequencing platforms and assays, used in cancer genomic testing services, we intend to take necessary measures to meet such requirements. Any failure to meet existing and future requirements may adversely affect our business and results of operations.

If we fail to obtain applicable licenses or registrations for our IVD medical products, we will be unable to commercially manufacture, distribute and market our products, and our commercialization of IVD medical products might be substantially harmed.

Our IVD medical products are subject to extensive regulations in China. To produce and sell our IVD medical products, we need to obtain licenses and registrations from the NMPA or its respective provincial counterparts. The sale of unregistered IVD medical products would result in administrative punishments including but not limited to monetary penalties. We currently have obtained approvals for four IVD assays, including an EUA for our COVID-19 detection kit issued by the FDA in the United States, and four IVD platforms, and most of our IVD medical products are still in development or in the process of obtaining registrations. The NMPA registration process is costly, lengthy and uncertain. In particular, we are required to conduct, at our own expenses, adequate and well-controlled clinical trials, and provide the NMPA with clinical data that demonstrate the efficacy and safety of our IVD medical products. The time required to obtain registrations from the NMPA is unpredictable but it typically takes years following the commencement of pre-clinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, registration policies, regulations or the type and amount of clinical data necessary to gain registration may change during the course of clinical development and may vary among regions. If we cannot obtain applicable registrations for our IVD medical products, we cannot commercialize such IVD medical products, which will have a material adverse effect on our business, financial condition and results of operations. We cannot control whether planned clinical trials will begin on time or whether any of our clinical trials will be completed on schedule, or at all. Our product development costs would likely increase if we encounter delays in testing or obtaining approvals or if we need to perform more or a larger scale of clinical trials than planned. If the delays are significant, the commercial prospects for some of our IVD medical products will be harmed, which will adversely affect our business and results of operations.

We face risks associated with uncertainties related to the PRC Regulation for the Administration of Human Genetic Resources.

The collection, preservation, usage and outbound provision of human genetic resources in the PRC are governed by PRC Regulation for the Administration of Human Genetic Resources (the “HGR Regulation”), except for activities related to human genetic resources conducted for some specific purposes including clinical diagnosis and treatment. The PRC Biosecurity Law promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”), on October 17, 2020 and came into effect on April 15, 2021 also confirms the principle that relevant activities related to human genetic resources are subject to the approval of the competent governmental authority, other than the collection and preservation of human genetic resources and related activities for the purposes of clinical diagnosis and treatment or for certain other purposes. Based on our consultation with the competent governmental authority, we believe that our diagnosis and monitoring business and early screening business are both for the purposes of clinical diagnosis and treatment, so that such activities related to human genetic resources in our diagnosis and monitoring business or early screening business may not be governed by the HGR Regulation nor required to be approved by relevant government authority. However, we cannot assure you that our diagnosis business and early screening business will be continuously deemed as being conducted for the purposes of clinical diagnosis and treatment by the relevant government authority. If such business is not deemed as for the purpose of clinical diagnosis and treatment, additional regulatory requirements including regulatory approvals may be required. Meanwhile, our collection, preservation and usage of human genetic resources in our development services are governed by the HGR Regulation.

Pursuant to the HGR Regulation, there are some limitations for foreign entities, individuals and such entities established or actually controlled thereby (“Restricted Entities”, and each, a “Restricted Entity”) to engage in activities related to human genetic resources. For example, the Restricted Entity is not allowed to collect or preserve human genetic resources of China, while it is prohibited from using human genetic resources of China unless that such Restricted Entity have obtained an approval from relevant government authority or have filed with relevant government authority for international cooperation with a domestic entity. The MOST has published the Draft of Implementation Rules for HGR Regulation for public comments on March 21, 2022, pursuant to which the VIE entity controlled by a foreign entity through contractual arrangements will be regarded as a Restricted Entity. Although the Draft of Implementation Rules for HGR Regulation for public comments has not been formally adopted, the VIE entities have been deemed as the Restricted Entities by the relevant governmental authority in practice. As a result, our development services will be required to be carried out through collaborations with domestic PRC entities, and we are required to obtain approvals or file with relevant government authority for such collaborations on development services, which could result in additional cost and our business, financial condition and results of operations may be adversely affected. As of the date of this annual report, we had not been subject to any material fines or other penalties related to our collection, preservation and usage of human genetic resources in our development services. However, regulatory agencies in China may periodically, and sometimes abruptly, change their enforcement practices. Therefore, prior enforcement activity, or lack of enforcement activity, is not necessarily predictive of future actions. The regulatory framework for the administration of human genetic resources is also evolving and may remain uncertain for the foreseeable future.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, investigation or sanction by regulatory authorities, private litigation, other liabilities, and/or adverse publicity. Non-compliance or failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data. This evolution may create uncertainty in our business, affect our or our collaborators’, service providers’ and contractors’ ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal data, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. We operate in an environment where privacy, cybersecurity and data protection laws and regulations are constantly evolving and requiring significant efforts of compliance. In our business, we collect and use our tested individuals’ personal data, including their age, gender, disease status and medical records, and we use such personal data internally to expand our database and improve our analytics approaches. We also share such personal data with third parties (e.g., service providers, hospitals and biopharmaceutical companies) both in China and globally for research and development, as well as other business purposes.

On November 7, 2016, the SCNPC issued the PRC Cybersecurity Law (“Cybersecurity Law”), which became effective on June 1, 2017. Pursuant to the Cybersecurity Law, network operators must not, without users’ consent, collect their personal information, and may only collect users’ personal information necessary to provide their 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 PRC Civil Code (issued by the PRC National People’s Congress on May 28, 2020 and effective from January 1, 2021) provides main legal basis for privacy and personal information infringement claims under the PRC civil laws. PRC regulators, including the CAC, MIIT, and the Ministry of Public Security have been increasingly focused on regulation in the areas of data security and data protection.

On June 10, 2021, the SCNPC promulgated the PRC Data Security Law, which became effective on September 1, 2021. The PRC Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data activities, and introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, as well as the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, or illegally acquired or used. The PRC Data Security Law also provides for a national security review procedure for data processing activities that may affect national security and imposes export restrictions on certain data and information. As uncertainties remain regarding the interpretation and implementation of these laws and regulations, we cannot assure you that we will comply with such regulations in all respects and we may be ordered to rectify or terminate any actions that are deemed illegal by regulatory authorities. We may also become subject to fines and/or other sanctions which may have material adverse effect on our business, operations and financial condition.

On August 20, 2021, the SCNPC promulgated the PRC Personal Information Protection Law (the “PIPL”), which became effective on November 1, 2021. In addition to other rules and principles of personal information processing, the PIPL specifically provides rules for processing sensitive personal information. Sensitive personal information refers to personal information that, once leaked or illegally used, could easily lead to the infringement of human dignity or harm to the personal or property safety of an individual, including biometric recognition, religious belief, specific identity, medical and health, financial account, personal whereabouts and other information of an individual, as well as any personal information of a minor under the age of 14. Only where there is a specific purpose and sufficient necessity, and under circumstances where strict protection measures are taken, may personal information processors process sensitive personal information. A personal information processor shall inform the individual of the necessity of processing such sensitive personal information and the impact thereof on the individual’s rights and interests. As uncertainties remain regarding the interpretation and implementation of the PIPL, we cannot assure you that we will comply with the PIPL in all respects and regulatory authorities may order us to rectify or terminate our current practice of collecting and processing sensitive personal information. We may also become subject to fines and/or other penalties, which may have material adverse effect on our business, results of operations and financial condition.

In addition, the Administrative Measures for Population Health Information (on Trial) promulgated by NHFPC and relevant regulations require medical service providers collecting or using population health-related information, including us, to ensure the information security and protect individual privacy. In addition, the Basic Standards and Administrative Norms of Medical Test Laboratory (on Trial), which was promulgated by the NHFPC and became effective on July 20, 2016, provides that medical test laboratories must establish information management and patient privacy protection policies. The increasing regulatory requirements in the PRC may lead to certain limitation to our use of the tested individuals’ personal data for improving our analytics or research and development of other new business.

Moreover, the PRC regulations related to cyber security and data security are constantly evolving. For example, on December 28, 2021, the Cyberspace Administration of China (“CAC”) and several other administrations published the Measures for Cybersecurity Review, effective on February 15, 2022. The Measures for Cybersecurity Review stipulate that an online platform operator who possesses personal information of over one million users and seeks to list its securities in a foreign country must be subject to the cybersecurity review. As of the date of this annual report, the number of users whose information possessed by us is far below one million. Additionally, substantial uncertainties exist with respect to the interpretation and implementation of the Measures for Cybersecurity Review. For example, it is unclear whether the requirement of cybersecurity review applies to follow-on offerings by an “online platform operator” that is in possession of personal data of more than one million users where the offshore holding company of such operator is already listed overseas. Earlier, the CAC also issued on November 14, 2021 a consultation draft of its Cyber Data Security Administration Regulations (“Draft Administration Regulations”), which, among other things, stipulates that a data processor listed overseas must conduct an annual data security review by itself or by engaging a data security service provider and submit the annual data security review report for a given year to the municipal cybersecurity department before January 31 of the following year. As of the date of this annual report, the Draft Administration Regulations has not been formally adopted. However, if it were enacted in the current form, we, as an overseas listed company, will be required to carry out an annual data security review and comply with the relevant reporting obligations. As of the date of this annual report, we have not been involved in any investigations on cybersecurity review made by the CAC on the national security basis or any other basis, and have not received any inquiry, notice, warning, or sanctions in such respect. However, we cannot guarantee that we will not be subject to any cybersecurity review in any future offering of securities outside the PRC.

Any failure or perceived failure to comply with applicable privacy, data protection and cyber security laws and regulations could result in reputational damage or proceedings or actions against us by governmental authorities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, and materially harm our business, prospects, financial condition and results of operations. Furthermore, a data breach affecting personal data could result in significant legal and financial exposure and reputational damage that could potentially have an adverse effect on our business.

We rely on third parties to monitor, support and/or conduct our pre-clinical studies and clinical trials. Therefore, we may not be able to directly control the timing, conduct, expense and quality of our clinical trials and we cannot assure you that these third parties can duly perform their obligations as agreed and expected.

We primarily rely on third-party hospitals to monitor, support, conduct pre-clinical studies and clinical trials of our cancer genomic testing pipeline products. As a result, we have less control over the quality, timing and cost of these studies and the ability to recruit trial subjects than conducting these trials entirely by ourselves. We cannot assure you that these third-party hospitals can meet expected timetable or can always be in compliance with regulatory requirements. Any failures of these third-party hospitals to duly perform their obligations may result in our clinical trials being extended, delayed or terminated, or our data being rejected by the NMPA or other regulatory agencies. In addition, if we are unable to maintain or enter into agreements with these third-party hospitals on acceptable terms, or if any such engagement is terminated, we may be unable to recruit trial subjects on a timely basis or otherwise conduct our trials in the manner we anticipate.

“Research use only (RUO)” and “investigational use only (IUO)” products could become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

Because RUO and IUO products are not intended for use in clinical practice and cannot be advertised or promoted for clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled “For Research Use Only. Not for use in diagnostic procedures,” and that IUO products be labeled “For Investigational Use Only. The performance characteristics of this product have not been established,” such products are not subject to the FDA’s pre- and post-market controls for medical devices.

A significant change in the laws governing RUO or IUO products or how they are enforced may require us to change our business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only,” or the RUO/IUO Guidance, which highlights the FDA’s interpretation that distribution of RUO or IUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as an LDT is in conflict with the RUO or IUO status. The RUO/IUO Guidance further articulates the FDA’s position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, is in conflict with RUO or IUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO or IUO status held by any of our products so labeled, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO or IUO products in a manner that is inconsistent with its RUO/IUO Guidance, we may be forced to stop distribution of our RUO/IUO tests until we are in compliance, which would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In the event that the FDA requires, or we apply for, marketing authorization of RUO or IUO products in the future, there can be no assurance that the FDA will grant any clearance or approval requested by us in a timely manner, or at all.

The regulatory pathways for our detection kit for the novel coronavirus (Genetron SARS-CoV-2 RNA Test), the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges that could adversely impact our business.

Our detection kit for the novel coronavirus (Genetron SARS-CoV-2 RNA Test), the virus that causes COVID-19, received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (the “FDA”) in June 2020. The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. However, commercialization under an EUA is permitted only during the underlying public health emergency (as declared by the Secretary of the Department of Health and Human Services), meaning that once the emergency declaration is terminated, we would be required to obtain FDA approval to continue marketing the product. Furthermore, the FDA may revoke an EUA based on a determination that the product no longer satisfies the criteria for issuance of an EUA—for example, if there is no longer evidence of effectiveness of the product or there are other adequate, approved alternatives. Accordingly, we cannot predict how long, if at all, an EUA for Genetron SARS-CoV-2 RNA Test may remain in place. FDA policies regarding diagnostic tests, therapies and other product used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized tests, necessitate additional measures or make it impractical or impossible for us to market our test. Any termination or revocation of the EUA for Genetron SARS-CoV-2 RNA Test could adversely impact our business.

Even though we have received breakthrough device designation for our HCCscreen™ for hepatocellular carcinoma, this designation may not expedite the development or review of HCCscreen™ and does not provide assurance ultimately of premarket approval submission or approval by the FDA.

The Breakthrough Devices Program is a voluntary program intended to expedite development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed.

Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. We obtained breakthrough device designation for HCCscreen™, a blood-based next-generation sequencing test, for “the qualitative detection of hepatocellular carcinoma (HCC)-associated DNA mutations and methylated DNA in cell-free DNA (cfDNA), and protein biomarkers derived from peripheral blood specimens” and “is intended for early detection of HCC in individuals who are designated to be at high-risk for hepatocellular carcinoma due to chronic HBV infection and/or liver cirrhosis.” However, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. For example, the time required to identify and resolve issues related to manufacturing and controls, the acquisition of a sufficient supply of our product for clinical trial purposes or the need to conduct additional nonclinical or clinical studies may delay approval by the FDA, even if the product qualifies for breakthrough designation or access to any other expedited program. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for the product.

The regulatory environment of medical devices, including IVD medical products, is constantly evolving. Our products and any future products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements.

Our products and any additional product candidates that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China, the United States and/or other jurisdictions where we market or sell our products.

Regulatory approvals for our products and any approvals that we receive for our product candidates are and may be subject to limitations on the indicated uses for which our product may be marketed. The approvals we obtain may also be subject to other conditions that may require potentially costly post-market testing and surveillance to monitor the safety and efficacy of our products or product candidates. Such limitations and conditions could adversely affect the commercial potential of our products. The NMPA and other comparable regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products placed on the market. Products may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. As such, we are and will be subject to continual review and inspections by the regulators to assess our compliance with applicable laws, requirements, and adherence to commitments we made in any application materials with the NMPA or other comparable regulatory authorities. Accordingly, we must continue to devote time, money and effort to all areas of regulatory compliance.

If we fail to maintain compliance with these ongoing regulatory requirements or if problems occur after our products reach the market, the NMPA or other comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval. Later discovery of previously unknown problems with our products or product candidates or with our manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or commercialization of our products, withdrawal of the products from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or
- injunctions or the imposition of civil, administrative or criminal penalties.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to the Clinical Laboratory Improvement Amendment of 1988 (“CLIA”), which is a U.S. federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory in the United States is located in Maryland and must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We currently hold CLIA certificates to perform high-complexity testing for our laboratories in Maryland and Beijing. Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing less complex testing. CLIA regulations require clinical laboratories like ours to comply with various operational, personnel, facilities administration, quality, and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is a prerequisite for reimbursement eligibility for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of compliance, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. In the event that we commence performing diagnostic tests in our Maryland laboratory, we must maintain CLIA compliance and certification to be eligible to bill for assays provided to federal healthcare program beneficiaries, including Medicare and Medicaid. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses in doing so.

Additionally, certain states in the United States require laboratory licenses in order to test specimens from patients in those states or received from ordering physicians in those states. We may also be subject to regulation in other jurisdictions if we seek to expand international distribution of our assays outside the United States.

If we were to lose our CLIA certification or state laboratory licenses, whether as a result of a revocation, suspension or limitation, we would not be able to offer our assays in the U.S. or any state for which we did not have a laboratory license in good standing, which would limit our future revenues and harm our business.

If we fail to comply with United States federal and state healthcare laws and regulations in connection with our activities in the United States, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

In the U.S., we are also subject to healthcare fraud and abuse regulation by both the federal government and the states in which we conduct our business. These laws include, without limitation:

- the federal Anti-Kickback Statute that prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service, including laboratory services, reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs;
- the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibit, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral;
- the federal civil and criminal false claims law, including the False Claims Act, that prohibits, among other things, any person from knowingly presenting or causing to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to get a false or fraudulent claim paid by the federal government;

- the federal civil monetary penalties statute, which prohibits, among other things, the offering or transferring to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that a person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, unless an exception applies;
- the federal Physician Payments Sunshine Act, which, among other things, imposes new reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by the statute) and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and applicable laws and regulations in other jurisdictions, including anti-kickback, false claims, consumer protection, and unfair competition laws that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangement as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require healthcare companies to comply with the industry's voluntary compliance guidelines, the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers, and other potential referral sources or state-specific standards on financial interactions with healthcare providers; and
- state laws that require healthcare companies to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation, and other remuneration and items of value provided to healthcare professionals and entities.

Our business practices, in operating a U.S. clinical laboratory, may face heightened scrutiny from U.S. government enforcement agencies such as the DOJ, the HHS Office of Inspector General (the "OIG"), and CMS. The OIG has issued fraud alerts in recent years that identify certain arrangements between clinical laboratories and referring physicians as implicating the federal Anti-Kickback Statute. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from the patient. Moreover, the provision of payments or other items of value by a clinical laboratory to a referring physician could be prohibited under the Stark Law, unless the arrangement meets all criteria of an applicable exception. The government has actively enforced these laws against clinical laboratories in recent years.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available and lack of clear guidance, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare and other applicable laws may involve substantial costs. In the future, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or then-existing statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare or applicable laws and regulations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and/or criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in U.S. federal or state health care programs, such as Medicare and Medicaid in the U.S. and similar programs outside the U.S., a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may ultimately lead to delay or denial of regulatory clearance or approval. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the regulatory authorities will agree with our conclusions regarding them. The clinical trial process may fail to demonstrate that our tests are safe and effective for the proposed indicated uses, which could cause us to abandon development of our tests and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, may impact our ability to commercialize our tests and generate revenues.

We may face intense competition and our competitors may develop similar, but more advanced services and products than ours, which may adversely affect our business and financial conditions.

We compete with life sciences companies that design, manufacture, and market products for analysis of genetic variations and biological functions and other applications using a wide range of competing technologies in the PRC and overseas. We anticipate that we will continue to face increased competitions as existing companies develop new or improved products and as new companies enter the market with new technologies. One or more of our competitors may render one or more of our technologies obsolete or uneconomical. Some of our competitors have greater financial, technical and personnel resources, broader or more focused product lines, a more established customer base, and more experience in research and development than we do. In addition, as a result of mergers and acquisitions in life science industry, even more resources are being concentrated in our competitors and our upstream and downstream business partners. Competition may increase further due to the progress or improvements made in the commercial applicability of technologies and the increased capital investment in the industries. Our competitors may develop products which are more effective, less costly and safer than we are able to, or obtain patent protection, regulatory approval, product commercialization, and market penetration more rapidly than we do.

Furthermore, life sciences, clinical genomics, and pharmaceutical companies, which are our potential customers and strategic partners, could also develop competing products, which may result in the decrease of demand of our services and products. Furthermore, we believe that customers in our markets display a significant amount of loyalty to their initial supplier of a particular product; therefore, it may be difficult to generate sales to potential customers who have purchased products from competitors. To the extent we are unable to be the first to develop or supply new services and products, our competitive position may suffer.

The market for cancer genomics is currently limited and highly competitive, with several large companies already having intellectual property portfolios and regulatory expertise. As a result, these companies may obtain regulatory approval more rapidly than we are able to. Established diagnostic companies also have an installed base of instruments in several markets, including clinical and reference laboratories, which could deter acceptance of our services and products. In addition, some of these companies have formed alliances with genomics companies that provide them with the access to genetic information that may be incorporated into their diagnostic tests, potentially creating a competitive advantage for them.

We and our competitors also compete on the basis of price. As the cost of analyzing genetic variation and biological function falls over time, as we expect, we cannot be sure that the demand for related services and products will increase proportionately. In the future, if the demand for our services and products proves to be more insensitive to lower sequencing costs than we expect, our business, financial condition, and results of operations will be adversely affected.

Security breaches, loss of data, and other disruptions may compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which may adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including health-related information, personally identifiable information, financial information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payers, and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of business-critical information, including research and development information, patient data, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit, and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data.

The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure, and the information technology systems and applications of our vendors, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other malicious or inadvertent disruptions. In addition, while we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. As a result of the COVID-19 pandemic, we and our third party service providers and partners may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Our third-party service providers and partners are also subject to these heightened risks. Unauthorized access, loss, or dissemination could also result in delays of our services and products development and commercialization as well as damage our reputation, including our ability to conduct our analysis, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

Any such unauthorized access, loss, or dissemination of information could also result in legal claims or proceedings, liabilities under PRC laws and regulations in relation to the protection of personal information and cybersecurity as well as those specifically governing patient and medical data. We have established, maintained and executed such internal system and are in the process of implementing further strengthened internal system to safeguard relevant health-related data. The costs to us to investigate and mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems from system failure, accident and security breach, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, disruption of our development programs and our business operations, cessation of service, negative publicity and other harm to our business and our competitive position, whether due to a loss of our trade secrets or other proprietary information or other disruptions.

We rely on a limited number of suppliers for some of our equipment and laboratory materials and may not be able to find replacements or immediately transition to alternative suppliers. A significant interruption in the operations of our suppliers could potentially affect our operations and any material misconduct or disputes against our suppliers could potentially harm our business and reputation.

We rely on several suppliers for some of our equipment and laboratory materials used in the chemical reactions incorporated into our processes, reagents, sequencing platforms and other materials that we use in our operations. In 2019, 2020 and 2021, we purchased the majority of our laboratory equipment and supplies from a limited number of suppliers. An interruption in our operations could occur if we encounter delays or difficulties in securing these reagents, sequencers, or other laboratory materials, and if we cannot then obtain an acceptable substitute. Any such interruption could negatively impact the research and development and launches of new services, and materially and adversely affect our business, financial condition, results of operations, and reputation. In addition, any material misconduct or disputes against our suppliers could potentially affect our business and reputation.

We believe that there are only a few other qualified equipment manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations. The use of equipment or materials furnished by these replacement suppliers would require us to significantly alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations and would likely affect the performance specifications of our laboratory operations. There can be no assurance that we would be able to secure alternative equipment, reagents, sequencing platforms and other materials without experiencing interruptions in our workflow. In the case of an alternative supplier, there can be no assurance that the equipment or materials supplied would be available or meet our quality control and performance requirements for our laboratory operations. If we should encounter any delay or difficulties in securing, reconfiguring, or revalidating the equipment, our business financial condition, results of operation, and reputation could be adversely affected.

We rely on third-party suppliers for certain of our raw materials, medical devices and components, as well as other third-party service providers, for different aspects of our business. If shipments from these suppliers are delayed or interrupted, or if the quality of the materials, medical devices, or components supplied do not meet our requirements, we may not be able to launch, manufacture, or ship our products in a timely manner, or at all. In addition, we may not always source raw materials and equipment on commercial reasonable terms. Furthermore, if third-party service providers can no longer provide satisfactory service to us on commercially reasonable terms, our business and results of operation may experience adverse impact.

We require customized, precision-manufactured sub-assemblies, components, and materials that currently are available from a limited number of sources, and, in the case of some sub-assemblies, components, and materials, from only a single source. If deliveries from these vendors are delayed or interrupted for any reason, or if we are otherwise unable to secure a sufficient supply, we may not be able to obtain these sub-assemblies, components, or materials on a timely basis, in sufficient quantities, or at satisfactory qualities, or at all, in order to meet demand for our precision oncology services and products. We may need to enter into contractual relationships with manufacturers for commercial-scale production of some of our products and supplies, in whole or in part, or develop these capabilities internally, and there can be no assurance that we will be able to do this on a timely basis, in sufficient quantities, or on commercially reasonable terms, especially the increase in price of equipment and raw materials would directly affect our financial results. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort required to qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Accordingly, we may not be able to establish or maintain reliable, high-volume manufacturing at commercially reasonable costs or at all. In addition, the manufacture or shipment of our products may be delayed or interrupted if the quality of the products, sub-assemblies, components, or materials supplied by our vendors does not meet our requirements. Current or future social and environmental regulations or critical issues, the need to eliminate environmentally sensitive materials from our products, could restrict the supply of components and materials used in production or increase our costs. Any delay or interruption to our manufacturing or shipping our products could result in lost revenue, which would adversely affect our business, financial condition, and results of operations.

We depend on third-party service providers for different aspects of our business, such as delivering samples for our testing services. Selecting, managing and supervising these third-party service providers requires significant resources and expertise. Unsatisfactory performance by these third-party service providers, including their failure to provide services according to applicable legal and regulatory requirements, the terms of our contracts or otherwise below standard, could significantly and negatively affect the quality of our services and damage our reputation.

If we encounter difficulties enrolling patients or collecting samples in our clinical trials, our research and development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion or sufficient samples. We may experience difficulties in patient enrolment or sample collection in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population or samples;
- the qualified patients or samples defined in the protocol;
- the size of the study population or samples required for analysis of the trial's primary endpoints;
- perceived risks and benefits our pipeline products;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to obtain and maintain required consent to use patients' information and samples; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials may compete with our competitors' clinical trials for cancer genomic testing product candidates that are in the same areas as our cancer genomic testing product candidates. Such competition will reduce the number and types of patients or samples available to us. Even if we are able to enroll a sufficient number of patients or collect sufficient samples in our clinical trials, delays in patient enrolment or sample collection may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our cancer genomic testing product candidates.

Our success depends on our ability to provide reliable, high-quality genomic testing services and products and to rapidly evolve to meet our customers' needs. If our products, or cancer genomic testing services and products available in the market, in general, do not meet the expectations of customers, our operating results, reputation and business could suffer.

Errors, including if our tests fail to accurately detect gene variants, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business. We classify variants in accordance with guidelines that are subject to change and subject to our interpretation. There can also be flaws in the databases, third-party tools, algorithms we use, and in the software that handle automated parts of our classification protocol. If we receive poor quality or degraded samples, our tests may be unable to accurately detect gene variants, or we may fail to or incompletely or incorrectly identify the significance of gene variants, which could have a significant adverse impact on our business. In addition, patients usually rely on the interpretations of doctors or physicians to read our testing reports and we are not able to ensure the interpretation will be correct and completed. Inaccurate results or misunderstandings of, or inappropriate reliance on, the information we provide to our customers could lead to, or be associated with, side effects or adverse events in patients who use our tests, including treatment-related death, and could lead to termination of our services or claims against us. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We do not maintain liability insurance, including for errors and omissions, and professional liability. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance premium rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests or cause a suspension of our license to operate. The occurrence of any of these events could have an adverse effect on our business, reputation and results of operations.

In addition, our success depends on the market's confidence in cancer genomic testing services and products in general. If other genetic based precision oncology products do not perform to expectations, it may result in lower confidence in our industry in general and will then adversely affect our business.

If our services or products do not meet the expectations of patients and/or our customers, our operating results, reputation and business could suffer.

Our success, to some extent, depends on the patients or our customers confidence that we can provide reliable, high-quality precision oncology services and products that will improve clinical outcomes, lower healthcare costs and enable better biopharmaceutical development.

We believe that patients, clinicians and biopharmaceutical companies are likely to be particularly sensitive to product defects, errors or inability to produce clinical reports in the use of our services or products. Our ability to provide reliable high-quality precision oncology services and products, including detecting genomic alterations with high accuracy and producing clinical reports, depends on the quality of samples that patients and/or our customers sent to us for examination. In the event that the collected samples do not meet our testing requirements, we may not be able to detect genomic alterations with high accuracy or produce clinical reports that meet their expectations. As a result, the failure of our products or our competitors' products to perform as expected could significantly impair our operating results and our reputation.

If our current research collaborators terminate their relationships with us or develop relationships with a competitor, our ability to discover genes, proteins, and biomarkers, and to validate and commercialize molecular diagnostic and companion diagnostic tests could be adversely affected.

The responsibility of overseeing research and development of our services and products is concentrated among a number of key research collaborators. There can be no assurance that there will not be a detrimental impact on us if one or more of these key research collaborators were to cease relationship with us, potentially as a result of lateral recruitment by existing or new competitors. As a result, this may adversely affect our ability to discover genes, proteins, and biomarkers, and to validate and commercialize molecular diagnostic and companion diagnostic tests.

Furthermore, our ability to continue to conduct and expand operations depends on our ability to attract and retain a large and growing number of personnel. The ability to meet our expertise needs, including the ability to find qualified personnel to fill positions that become vacant at our research and development department or to collaborate with us in research and development efforts, while controlling our costs, is generally subject to numerous external factors, including the availability of a sufficient number of qualified persons in the cancer genomics markets in which our business operates, the unemployment levels within those markets, prevailing wage rates, changing demographics, health and other insurance costs and adoption of new or revised employment and labor laws and regulations. If we are unable to locate, to attract or to retain qualified personnel, the quality of services and products provided to customers may decrease and our financial performance may be adversely affected. In addition, if costs of labor or related costs to maintain relationships with research collaborators increase for other reasons or if new or revised labor laws, rules or regulations or healthcare laws are adopted or implemented that further increase labor costs, our business, financial condition and results of operations could be materially adversely affected.

We may fail to maintain sufficient marketing and sales capabilities.

We mainly rely on our in-house specialized sales and marketing team to directly market and sell our services and products. Maintaining such in-house teams may require significant expenses, management resources and time. We will have to compete with other life sciences, clinical genomics, and pharmaceutical companies to recruit, hire, train and retain suitable personnel. We also continuously train our in-house sale force to ensure them to implement sales and marketing efficiently and in compliance with laws and regulations as well as our internal policies.

In addition to our direct sales, we also sell our products to hospitals through our distributors. We may have little control over the marketing and sales efforts of such third parties, and our revenue from distributor sales may be lower than commercializing ourselves.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any services or products, and as a result, our financial condition and results of operations may be adversely effected if we are unable to generate sales revenue.

Reimbursement may not be immediately available for our services and products, which could diminish our sales or affect our profitability.

China has a complex medical insurance system that is currently undergoing reform. Governmental insurance coverage or the reimbursement rates in China for treatments using new medical devices and healthcare services are subject to uncertainty and vary from region to region, as local government approvals for such coverage must be obtained in each geographic region. In addition, the PRC government may change, reduce or eliminate the governmental insurance coverage currently available for treatments based on a number of factors, including price and efficacy.

Currently, our services and products are not eligible for reimbursement. Therefore, our customers need to bear the test prices themselves. The limitation on reimbursement of our service and products will adversely affect our sales, profitability and growth.

RISKS RELATED TO OUR OPERATIONS

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our services and products through continued research and development efforts, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our services and products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development and commercialization efforts effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

In addition, as our business enter into new geographic regions, we will invest substantial resources and face new operational risks and challenges associated with the business, economic and regulatory environment that we are not familiar with. We will be required, among other things, to understand and comply with the local regulations, to partner with local healthcare industry, and to meet the expectations of local customers.

If we are unable to support demand for our existing or future precision oncology services and products, including ensuring that we have adequate capacity to meet increased demand, our business could suffer.

As our volume grows, we will need to continue to increase our workflow capacity for sample intake, customer service, billing, and general process improvements; expand our internal quality assurance program; and extend our services and products to support comprehensive genomic analysis at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and technicians and other scientific and technical personnel to process higher volumes of our services. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up, and validate, and increase our software and computing capacity to meet increased demand. The expansion of our operations or hiring of additional personnel may lead to significant costs and divert our management attentions and development resources. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facilities to accommodate such required expansion.

As we commercialize additional services, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher service costs, declining service quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our services, and could damage our reputation and the prospects for our business.

We face risks related to health epidemics, including COVID-19, severe weather conditions and other outbreaks.

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the COVID-19 coronavirus outbreak a public health emergency of international concern and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographies in which we operate. As a result, the demand for our precision oncology services and products was adversely affected in both 2020 and 2021. In 2020, we sold approximately 21,900 diagnostic tests, compared to approximately 22,900 diagnostic tests in 2019. In 2021, we sold approximately 24,360 diagnostic tests. In addition to the impact on our financial performance, COVID-19 also had temporary negative impact on our business activities, including our HIT Study and advancement of our IVD pipeline registration process.

Due to the continued enforcement of the “zero COVID” strategy in China and the resulting sustained travel restrictions across our major markets in China, the number of cancer patients that visited hospitals we covered decreased. In addition, intermittent COVID outbreaks continued to occur across China since the fourth quarter of 2021 and well into the first quarter of 2022, hence PRC government have maintained the zero-COVID policy through lockdowns, mass testing, and travel restrictions. More recently, rapidly soaring COVID cases had resulted in shutdowns in the cities of Beijing, Shenzhen and Shanghai, as well as parts of Shandong and Jilin provinces. In March 2022, Shanghai has began its most extensive large-scale lockdown in two years, highlighting the continued significant challenges posed by the virus. As such, the demand for our precision oncology services and products was adversely affected in 2021. The potential impact brought by and the duration of the COVID-19 outbreak is difficult to assess or predict and the full impact of the virus on our operations will depend on many factors beyond our control, including the extent of resurgences of the disease and its variants, vaccine distribution and other actions in response to the virus or to contain its impact. Our business operations may be further adversely affected, if hospitals, our direct sales team, distributors or other business partners continue to be affected by COVID-19. While it is unknown how long these conditions will last and what the complete financial effect will be to our Company, we are closely monitoring their impact on us. Our business, results of operations, financial conditions and prospects could be materially adversely affected to the extent that COVID-19 harms the Chinese and global economy in general, and the trading price of the ADSs may be adversely affected.

In addition to COVID-19, our business could be adversely affected by the effects of avian influenza, severe acute respiratory syndrome (SARS), the influenza A virus, Ebola virus, severe weather conditions or other epidemics or outbreaks. Health or other government regulations adopted in response to epidemics, severe weather conditions such as snowstorms, floods or hazardous air pollution, or other outbreaks may require temporary closure of our offices. Such closures may disrupt our business operations and adversely affect our results of operations.

We may not be able to attract and retain key senior management members and research and development personnel.

Our future success depends upon the continuing services of members of our senior management team and key research and development personnel and consultants. In particular, Mr. WANG Sizhen, our Chief Executive Officer, Dr. YAN Hai, our Chief Scientific Officer, Dr. JIAO Yuchen, our Chief Technology Officer, Mr. XU Ce, our Chief Financial Officer, and Dr. HU Yun-Fu, our Chief Medical Officer are crucial to our research and development and operations. Although we typically require our key personals to enter into non-compete and confidentiality agreements with us, we cannot prevent them from joining our competitors after the non-compete period. The loss of their services could adversely impact our ability to achieve our business objectives. If one or more of our senior management or key clinical and scientific personnel are unable or unwilling to continue serving us, join a competitor, or form a competing company, we may not be able to replace them in a timely manner or at all, which will have a material and adverse effect on our business, financial condition and results of operations. We do not maintain any “key person” insurance for any of our executives or other employees.

In addition, the continued growth of our business depends on our ability to hire additional qualified personnel with expertise in molecular biology, chemistry, biological information processing, software, engineering, sales, marketing, and technical support. We compete for qualified management and scientific personnel with other life science and technology companies, universities, and research institutions in the PRC and overseas. Competition for these individuals is intense, and the turnover rate can be high. Failure to attract and retain management and scientific and engineering personnel could prevent us from pursuing collaborations or developing our services and products or technologies.

Past and future grants of share-based awards may have an adverse effect on our financial condition and results of operations and have dilutive impact to your investment.

We adopted 2019 Plan in July 2019 and 2019 Scheme in November 2019, to enhance our ability to attract and retain exceptionally qualified individuals and to encourage them to acquire a proprietary interest in the growth and performance of us. The maximum aggregate number of ordinary shares we are authorized to issue pursuant to all awards under the 2019 Plan is 33,961,500 ordinary shares. The maximum aggregate number of ordinary shares we are authorized to issue pursuant to all awards under the 2019 Scheme is 20,830,100 ordinary shares. See “Item 6. Directors, Senior Management and Employees—6.B. Compensation—Share Incentive Plan.”

For the years ended December 31, 2019, 2020 and 2021, we recorded RMB35.9 million, RMB30.0 million and RMB54.1 million (US\$8.5 million), respectively, in share-based compensation expenses. We believe the granting of share-based awards is of significant importance to our ability to attract and retain key personnel and employees, and we will continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations.

If our laboratory facilities become contaminated, damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.

Although we have back-up measures in place for all of our laboratory facilities, the data and samples stored in our laboratory facilities are still subject to various risks beyond our control. While our multi-location laboratories help us weather operational breakdowns at any one location, our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fires, earthquakes, flooding, and power outages, which may render it difficult or impossible for us to sell or perform our services for some period of time. The inability to sell or to perform our diagnostic and other services, or the backlog of samples that could develop if our facility is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. Furthermore, our facilities and the equipment used to perform our services and our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples as the basis for the development of our services. In some cases, these samples are difficult to obtain. If the parts of our laboratory facility where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized.

We may pursue collaborations, in-licensing or out-license arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements, which may fail to produce anticipated benefits and adversely affect our operations.

We may pursue opportunities for collaboration, in-licensing, out-license, joint ventures, acquisitions of products, assets or technology, strategic alliances, or partnerships that we believe would be complementary to or promote our existing business. In particular, we intend to continue to pursue growth through the acquisition of technology, assets or other businesses that may enable us to enhance our technologies and capabilities, expand our market presence, add experienced management personnel and increase our test offerings. Proposing, negotiating and implementing these opportunities may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not be able to identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all.

We have limited experience with respect to these business development activities. Management and integration of a licensing arrangement, collaboration, joint venture or other strategic arrangement may disrupt our current operations, decrease our profitability, result in significant expenses, or divert management resources that otherwise would be available for our existing business. We may not realize the anticipated benefits of any such transaction or arrangement.

Furthermore, partners, collaborators, or other parties to such transactions or arrangements may fail to fully perform their obligations or meet our expectations or cooperate with us satisfactorily for various reasons and subject us to potential risks, including but not limited to the following:

- partners, collaborators, or other parties have significant discretion in determining the efforts and resources that they will apply to a transaction or arrangement;
- partners, collaborators, or other parties could independently develop, or develop with third parties, services and products that compete directly or indirectly with our services and products;
- partners, collaborators, or other parties may stop, delay or discontinue research and development, and commercialization efforts;
- partners, collaborators, or other parties may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and partners, collaborators, or other parties that cause the delay or termination of the research, development or commercialization of our services and products, or that result in costly litigation or arbitration that diverts management's attention and resources;
- our collaborative arrangements with partners, collaborators, or other parties may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable services and products; and
- partners, collaborators, or other parties may own or co-own intellectual property covering our services and products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any such transactions or arrangements may also require actions, consents, approval, waiver, participation or involvement of various degrees from third parties, such as regulators, government authorities, creditors, licensors or licensees, related individuals, suppliers, distributors, shareholders or other stakeholders or interested parties. There is no assurance that such third parties will be cooperative as we desire, or at all, in which case we may be unable to carry out the relevant transactions or arrangements.

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. Our laboratory facilities have received the CAP accreditation and NCCL EQA Certification.

However, despite our quality control management system, we cannot eliminate the risk 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 and services 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.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, suppliers and other contractors, could be subjected to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, health epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition.

Our employees, third-party suppliers, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, third-party suppliers, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the NMPA and overseas regulators that have jurisdictions over us, comply with healthcare fraud and abuse laws and regulations in China and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials or research studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and divert the attention of management in defending ourselves against any of these claims or investigations.

Our business depends on a strong brand, and failing to maintain and enhance our brand would adversely affect our business, results of operations and financial condition.

We believe that maintaining and enhancing our brand identity and increasing market awareness of our Company and products, particularly among clinicians and biopharmaceutical companies, is critical to achieving widespread acceptance of our services and products, to strengthening our relationships with our existing clients and to our ability to attract new clients. The successful promotion of our brand will depend largely on our ability to continue to offer high-quality services and products and our research and development efforts. Our brand promotion activities may not be successful or yield increased revenue.

In addition, if clients deem our testing results not accurate, then our brand and reputation may suffer, clients may lose confidence in us and they may reduce or cease their use of our services and products. Our clients may post and discuss on social media about our services and products. Our reputation depends, in part, on our ability to generate positive feedback and minimize negative feedback on social media channels where existing and potential clients seek and share information. If actions we take or changes we make to our services or products upset these clients, then their online commentary could negatively affect our brand and reputation. Complaints or negative publicity about us, our services or products could materially and adversely impact our ability to attract and retain clients, our business, results of operations and financial condition.

The promotion of our brand also requires us to make expenditures, and we anticipate that these expenditures will increase as our market becomes more competitive. To the extent that these activities increase revenue, this revenue still may not be enough to offset the increased expenses we incur. If we do not successfully maintain and enhance our brand, then our business may not grow, we may see our pricing power reduced relative to competitors and we may lose clients, all of which would adversely affect our business, results of operations and financial condition.

We depend on our information technology and other technology systems for significant elements of our operations, and any failure of the technology could harm our business.

We depend on our information technology for significant elements of our operations. For instance, we apply automated bioinformatics solutions, and our AI technology is able to automatically analyze DNA sequencing data to generate a ready-to-read data report. We have also installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling financial reporting and controls, customer relationship management, laboratory information management system, and other infrastructure operations.

Our information and other technology systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts and natural disasters. Our servers are potentially vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Although we have taken the precautionary measures to prevent unanticipated problems that could affect our information technology and telecommunications systems, we, or our third-party service providers, may experience failures or significant downtime of our information technology or telecommunications systems. These incidents could prevent us from conducting tests, preparing and providing reports to our customers, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

Our business, financial condition and results of operations, as well as our ability to obtain financing, may be adversely affected by a downturn in the global or China's economy.

The global macroeconomic environment is facing challenges, including the economic slowdown in the Eurozone since 2014 and uncertainties over the impact of Brexit. The growth of the China's economy has slowed down since 2012 compared to the previous decade and the trend may continue. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world's leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa. There have also been concerns on the relationship between China and the United States, including those resulting from the ongoing trade dispute between the two countries, which may potentially lead to foreign investors' closing down their business or withdrawing their investment in China and thus exiting the China market, and other economic effects. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policies and the expected or perceived overall economic growth rate in China.

Any prolonged slowdown in the global or China's economy may have a negative impact on our business, results of operations and financial condition, and continued turbulence in the international markets may adversely affect our ability to access the capital markets to meet liquidity needs. Our clients may reduce or delay spending with us, while we may have difficulty expanding our client base fast enough, or at all, to offset the impact of decreased spending by our existing clients. In addition, to the extent we offer credit to any client and the client experiences financial difficulties due to the economic slowdown, we could have difficulty collecting payment from such client. Moreover, a slowdown or disruption in the global or China's economy may have a material and adverse impact on the financing available to us. The weakness in the economy could erode investor confidence, which constitutes the basis of the credit market.

Since 2019, there have been heightened tensions in the economic relations between the U.S. and China. The U.S. government has imposed, and proposed to impose additional, new or higher tariffs on products imported from China to penalize China for what it characterizes as unfair trade practices. China has responded by imposing largely commensurate tariffs on products imported from the U.S. Amid these tensions, the U.S. government has imposed and may impose additional measures on entities in China, including sanctions. We currently source some of our reagents and laboratory equipment from vendors based in the U.S. The U.S. government may prohibit these companies from doing business with Chinese companies and the Chinese government may implement countermeasures. If this were to happen, we may be required to seek substitute suppliers, which could adversely affect our operations. Moreover, the potential increase in tariffs may also increase the costs we incur to purchase imported reagents and laboratory equipment.

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are subject to rules and regulations by various governing bodies, including, for example, the U.S. Securities and Exchange Commission, and the various regulatory authorities in China and the Cayman Islands, and we are also subject to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

Allegations or lawsuits against us or our management may harm our reputation and business.

We have been, and may in the future be, subject to allegations or lawsuits brought by our competitors, clients, employees or other individuals or entities, including claims of breach of contract.

In addition, we may be subject to product liability claims alleging that our services and products identified inaccurate or incomplete information regarding the genomic alterations of the tumor or malignancy analyzed, reported inaccurate or incomplete information concerning the available therapies for a certain type of cancer or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities.

Any such allegation or lawsuits, with or without merit, or any perceived unfair, unethical, fraudulent or inappropriate business practice by us or perceived malfeasance by our management could incur substantial expenses, delay or suspend our ongoing clinical trial, cause the withdrawal of clinical participants, harm our reputation, distract our management from our daily operations and result in other negative results. Allegations or lawsuits against us may also generate negative publicity that significantly harms our reputation, which may materially and adversely affect our user base and our ability to attract customers. In addition to the related cost, managing and defending litigation and related indemnity obligations can significantly divert management's attention. We may also need to pay damages or settle the litigation with a substantial amount of cash. All of these could have a material adverse impact on our business, results of operation and cash flows.

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.

The SEC, as required by Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, adopted rules requiring most public companies to include a management report on such company's internal control over financial reporting in its annual report, which contains the management's assessment of the effectiveness of the company's internal control over financial reporting. In addition, when a company meets the SEC's criteria, an independent registered public accounting firm must report on the effectiveness of the company's internal control over financial reporting.

We are a public company in the United States subject to the Sarbanes-Oxley Act of 2002. As described in our previous annual report of Form 20-F for the fiscal year ended December 31, 2020, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting as of December 31, 2020. The material weaknesses identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of IFRS and reporting requirements set forth by the SEC to address complex IFRS technical accounting issues, and to prepare and review the consolidated financial statements and related disclosures in accordance with IFRS and SEC reporting requirements; and (ii) our lack of formal and effective period-end financial closing policies and procedures. We have taken measures to remediate the identified material weaknesses. See “Item 15. Controls and Procedures—Remediation of Previously Reported Material Weaknesses in Internal Control over Financial Reporting.” As a result of these efforts, our management has concluded that our internal control over financial reporting was effective as of December 31, 2021. Our independent registered public accounting firm has issued an attestation report, which has concluded that we maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021.

However, we cannot assure you that in the future our management or our independent registered public accounting firm will not identify material weaknesses during the Section 404 of the Sarbanes-Oxley Act audit process. In addition, because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. If we fail to achieve and maintain an effective internal control environment, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of the ADSs. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. Furthermore, we have incurred and expect to continue to incur considerable costs and to use significant management time and the other resources in an effort to comply with Section 404 and other requirements of the Sarbanes-Oxley Act, which can significantly divert our management’s attention from operating our business.

If we fail to achieve and maintain an effective internal control environment, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of our ADSs. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the Nasdaq, regulatory investigations and civil or criminal sanctions.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.

The insurance companies in China currently offer limited business-related insurance products. We do not maintain business interruption insurance or general third-party liability insurance, nor do we maintain product liability insurance or key-man insurance. We consider this practice to be reasonable in light of the nature of our business and the insurance products that are available in China and in line with the practices of other companies in the same industry of similar size in China. Any uninsured risks may result in substantial costs and the diversion of resources, which could adversely affect our results of operations and financial condition.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We may be unsuccessful in obtaining or maintaining adequate intellectual property protection for one or more of our services and products, and our patents could be found invalid or unenforceable if challenged in court or before administrative bodies.

Our commercial success will depend, in large part, on our ability to obtain, maintain and defend patents and trademarks and the proprietary technologies covering our services and products and maintain some of our proprietary technologies as trade secrets. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our services and products, or otherwise provide us with any competitive advantage. Additionally, the patent applications in respect of patents licensed under our in-license arrangements may not be issued or granted, and as a result, we may not be able to have adequate protection with respect to such patents. The patent position of life sciences, clinical genomics and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we had applied may not be granted in the end. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owned interest in such patents or patent applications, we may not be able to license or transfer our rights to other third parties. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. As such, we do not know the degree of future protection that we will have on our services and products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our services and products could have a material adverse impact on our business.

Despite the fact that we can take measures to obtain patent and other intellectual property protections with respect to our services and products, there can be no assurance that the existence, validity, enforceability, or scope of our intellectual property rights will not be challenged by a third party, or that we can obtain sufficient scope of claim in those patents to prevent a third party from competing against our services and products. For example, in an infringement proceeding, a court may decide that patent rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the ground that our patent rights do not cover the technology in question. An adverse result in any litigation proceedings could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our services and products, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, be obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the China National Intellectual Property Administration, or the CNIPA, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our services and products. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Third parties may also raise similar claims before administrative bodies in the PRC or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and equivalent proceedings, such as opposition proceedings. Such legal proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our services and products. The outcome following legal assertions of invalidity and unenforceability can be unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose part or all of the patent protection on our services and products. Any loss of patent protection could have a material adverse impact on one or more of our services and products and our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, alleging that we infringed their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that our patents do not cover the other party's products and/or commercial activity. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the alleged infringing has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The life sciences industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our potential competitors in both the PRC and abroad may have substantially greater resources and are likely to make substantial investments in patent portfolios and competing technologies, and may apply for or obtain patents that could prevent, limit or otherwise interfere with our ability to make, use and sell our products. Numerous third-party patents exist in fields related to our products and technologies, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products and technologies. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products and technologies.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our technologies, products, and services. Regardless of the merit of third parties claims against us for infringement, misappropriation or violations of their intellectual property rights, such third parties may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, even if such claims are resolved in our favor, could cause us to incur substantial expenses and be a substantial diversion of our employee resources even if we are ultimately successful. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of the ADSs. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The CNIPA, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application and prosecution process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and/or applications will be due to be paid to the CNIPA and various other governmental patent agencies outside of China in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

We seek to protect our intellectual property and proprietary technologies, in part, by entering into agreements, including confidentiality agreements and non-disclosure agreements, with parties that have access to them, such as our employees, consultants, academic institutions, corporate partners and other third-party service providers. Nevertheless, there can be no guarantee that an employee or a third party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or business partners might intentionally or inadvertently disclose our trade secret information to competitors or our trade secrets may otherwise be misappropriated. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable.

We sometimes engage individuals or research institutions to conduct research relevant to our business. The ability of these individuals or research institutions to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized, which could adversely affect our business, financial condition and results of operations.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to independently develop similar or alternative technologies or designs that are similar to our services and products but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications may not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive services and products for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our services and products candidates for one or more cancer types.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Patent terms may not be sufficient to effectively protect our services and products and business.

In most countries in which we file and plan to file applications for patents, the term of an issued patent is generally 10 to 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if patents covering our services and products are obtained, we may be open to competition from other companies once our patent rights expire. Upon expiration of our issued patents, we will no longer have patent rights and will not be able to assert such patents against potential competitors and our business and results of operation may be adversely affected.

As of December 31, 2021, we owned or co-owned eight issued patents and 26 pending patent applications in China, one issued patent in the United States, one issued patent in South Korea, three pending patent applications in the United States, nine pending patent applications in Europe, Japan, South Korea and Singapore and two Patent Cooperation Treaty (“PCT”) applications that have not entered national stage. Our patents cover our key technologies, including Genetron One-Step Seq™ Method (Chinese Patent No. CN106835292) and liquid biopsy library construction sequencing analysis. As of December 31, 2021, we also owned 95 registered trademarks, copyrights to 40 software programs developed by us related to various aspects of our operations, and nine registered domain names. Our issued patents have expiration dates ranging from May 2030 to June 2041. If patents are issued on our pending patent applications, the resulting patents will be expected to expire between September 2035 to June 2041, subject to any potential patent term extension or adjustment. Upon expiration of our issued patent or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operation may be adversely affected.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. We may also encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the jurisdictions of the registration of our intellectual properties. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products. Our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may not be able to protect and enforce our trademarks.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

RISKS RELATED TO OUR CORPORATE STRUCTURE

There are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules relating to our contractual arrangements, including potential future actions by the PRC government, which could affect the enforceability of our contractual arrangements and, consequently, significantly affect our financial condition and results of operation. If the PRC government finds our contractual arrangements non-compliant with relevant PRC laws, regulations and rules, or if these laws, regulations and rules or the interpretation thereof change in the future, we could be subject to severe penalties or be forced to relinquish our interests in the VIEs.

Current PRC laws and regulations impose certain restrictions or prohibitions on foreign ownership of companies that engage in the development and application of technologies for diagnosis and treatment of human stem cells and genes, which our precision oncology service relates to. Pursuant to the Special Administrative Measures (Negative List) (2021 Version) for Foreign Investment Access issued by the NDRC and MOFCOM on December 27, 2021 (the “Negative List”), which came into force on January 1, 2022, certain industries are specifically prohibited for foreign investment, including the development and application of technologies for diagnosis and treatment of human stem cells and genes. To comply with PRC laws and regulations, we conduct our cancer genomics business in China through VIEs. We, through PRC Subsidiaries, our subsidiaries in China, entered into a series of contractual arrangements with the VIEs and their respective shareholders, in order to (i) enable us to have the power to direct the activities that most significantly affect the economic performance of the VIEs, (ii) receive substantially all of the economic benefits of the VIEs, and (iii) have an exclusive option to purchase all or part of the equity interests in the VIEs when and to the extent permitted by PRC law. As a result of these contractual arrangements, we have control over and are the primary beneficiary of each of the VIEs and hence consolidate their financial results under IFRS. Although the structure we have adopted is consistent with long-standing practice in certain industries, such as TMT industry, and is also adopted by some of our peers in China, the PRC government may not agree that these arrangements comply with PRC license, registration or other regulatory requirements, with existing policies, or with requirements or policies that may be adopted in the future. The VIEs hold the licenses, approvals and key assets that are essential for the operations of our precision oncology service businesses.

In the opinion of our PRC legal counsel, Shihui Partners, (i) the ownership structures of the VIEs in China, currently do not result in any violation of the applicable PRC laws or regulations currently in effect, and (ii) the contractual arrangements among PRC Subsidiaries, the VIEs and their respective equity holders governed by PRC laws are valid, binding and enforceable in accordance with their terms and applicable PRC laws and regulations currently in effect and do not violate any applicable PRC laws, rules or regulations currently in effect. There are, however, substantial uncertainties regarding the interpretation and application of current or future PRC laws and regulations. The relevant PRC regulatory authorities have broad discretion in determining whether a particular contractual structure violates PRC laws and regulations. Thus, we cannot assure you that the PRC government will not ultimately take a view contrary to the opinion of our PRC legal counsel. If we are found in violation of any PRC laws or regulations or if the contractual arrangements among PRC Subsidiaries, the VIEs and their respective equity holders are determined as illegal or invalid by any PRC court, arbitral tribunal or regulatory authorities, the relevant governmental authorities would have broad discretion in dealing with such violation, including, without limitation:

- revoking the agreements constituting the contractual arrangements;
- revoking our business licenses and/or operating licenses of such entities;
- restricting our right to collect revenue;
- shutting down all or part of our websites or services;
- levying fines on us and/or confiscating the proceeds that they deem to have been obtained through non-compliant operations;
- requiring us to restructure our ownership structure or operations, including terminating the contractual arrangements with the VIEs and deregistering the equity pledges of the VIEs, which in turn would affect our ability to consolidate, derive economic interests from, or exert effective control over the VIEs;
- imposing additional conditions or requirements with which we may not be able to comply;

- restricting or prohibiting our use of proceeds from public offering or other financing activities to finance our business and operations in China; or
- taking other regulatory or enforcement actions that could be harmful to our business.

Furthermore, any of the assets under the name of any record holder of equity interest in the VIEs, including such equity interest, may be put under court custody in connection with litigation, arbitration or other judicial or dispute resolution proceedings against that record holder. We cannot be certain that the equity interest will be disposed of in accordance with the contractual arrangements. In addition, new PRC laws, rules and regulations may be introduced to impose additional requirements that may impose additional challenges to our corporate structure and contractual arrangements. The occurrence of any of these events or the imposition of any of these penalties may result in a material and adverse effect on our ability to conduct our precision oncology service business. In addition, if the imposition of any of these penalties causes us to be unable to direct the activities of such VIEs and their subsidiaries or the right to receive their economic benefits, we would no longer be able to consolidate such VIEs into our financial statements, thus adversely affecting our results of operation and cause our ADSs to significantly decline in value or become worthless.

We rely on contractual arrangements with the VIEs and their shareholders for our business operations, which may not be as effective as direct ownership in providing operational control.

We have relied and expect to continue to rely on contractual arrangements with the VIEs and their shareholders to operate our business in China. These contractual arrangements may not be as effective as direct ownership in providing us with control over the VIEs. For example, the VIEs and their shareholders could breach their contractual arrangements with us by, among other things, failing to conduct their operations in an acceptable manner or taking other actions that are detrimental to our interests.

If we had direct ownership of the VIEs in China, we would be able to exercise our rights as a shareholder to effect changes in the board of directors of the VIEs, which in turn could implement changes, subject to any applicable fiduciary obligations, at the management and operational level. However, under the current contractual arrangements, we rely on the performance by the VIEs and their shareholders of their obligations under the contracts to exercise control over the VIEs. The shareholders of the VIEs may not act in the best interests of our Company or may not perform their obligations under these contracts. Such risks exist throughout the period in which we intend to operate certain portions of our business through the contractual arrangements with the VIEs. If any dispute related to these contracts remains unresolved, we will have to enforce our rights under these contracts through the operations of PRC law and arbitration, litigation and other legal proceedings and, therefore, will be subject to uncertainties in the PRC legal system. See “—Any failure by the VIEs or their shareholders to perform their obligations under our contractual arrangements with them would have a material adverse effect on our business.” Therefore, our contractual arrangements with the VIEs may not be as effective in ensuring our control over the relevant portion of our business operations as direct ownership would be.

Any failure by the VIEs or their shareholders to perform their obligations under our contractual arrangements with them would have a material adverse effect on our business.

If the VIEs or their shareholders fail to perform their respective obligations under the contractual arrangements, we may have to incur substantial costs and expend additional resources to enforce such arrangements. We may also have to rely on legal remedies under PRC law, including seeking specific performance or injunctive relief, and claiming damages, which we cannot assure you will be sufficient or effective under PRC law. For example, if the shareholders of the VIEs were to refuse to transfer their equity interests in the VIEs to us or our designee if we exercise the purchase option pursuant to these contractual arrangements, or if they were otherwise to act in bad faith toward us, then we may have to take legal actions to compel them to perform their contractual obligations.

All the agreements under our contractual arrangements are governed by PRC laws and provide for the resolution of disputes through arbitration in China. Accordingly, these contracts would be interpreted in accordance with PRC laws and any disputes would be resolved in accordance with PRC legal procedures. The legal system in the PRC is not as developed as in some other jurisdictions, such as the United States. As a result, uncertainties in the PRC legal system could limit our ability to enforce these contractual arrangements. Meanwhile, there are very few precedents and little formal guidance as to how contractual arrangements in the context of a consolidated variable interest entity should be interpreted or enforced under PRC laws. There remain significant uncertainties regarding the ultimate outcome of such arbitration should legal action become necessary. In addition, under PRC laws, rulings by arbitrators are final, and if the losing parties fail to carry out the arbitration awards within a prescribed time limit, the prevailing parties may only enforce the arbitration awards in PRC courts through arbitration award recognition proceedings, which would require additional expenses and delay. In the event we are unable to enforce these contractual arrangements, or if we suffer significant delay or other obstacles in the process of enforcing these contractual arrangements, we may not be able to exert effective control over the VIEs, and our ability to conduct our business may be negatively affected.

The shareholders of the VIEs may have actual or potential conflicts of interest with us, which may materially and adversely affect our business, results of operations and financial condition.

The shareholders of the VIEs may have actual or potential conflicts of interest with us. These shareholders may refuse to sign or breach, or cause the VIEs to breach, or refuse to renew, the existing contractual arrangements we have with them and the VIEs, which would have a material adverse effect on our ability to effectively control the VIEs and receive economic benefits from them. For example, the shareholders may be able to cause our agreements with the VIEs to be performed in a manner adverse to us by, among other things, failing to remit payments due under the contractual arrangements to us on a timely basis. We cannot assure you that when conflicts of interest arise any or all of these shareholders will act in the best interests of our Company or such conflicts will be resolved in our favor. Currently, we do not have any arrangements to address potential conflicts of interest between these shareholders and our Company, except that we could exercise our purchase option under the exclusive option agreement with these shareholders to request them to transfer all of their equity interests in the VIEs to a PRC entity or individual designated by us, to the extent permitted by PRC laws. If we cannot resolve any conflict of interest or dispute between us and these shareholders, we would have to rely on legal proceedings, which could result in disruption of our business and subject us to substantial uncertainty as to the outcome of any such legal proceedings.

Contractual arrangements in relation to the VIEs may be subject to scrutiny by the PRC tax authorities and they may determine that we or the VIEs owe additional taxes, which could negatively affect our financial condition and the value of your investment.

Under applicable PRC laws and regulations, arrangements and transactions among related parties may be subject to audit or challenge by the PRC tax authorities within ten years after the taxable year when the transactions are conducted. We could face material and adverse tax consequences if the PRC tax authorities determine that the contractual arrangements were not entered into on an arm's-length basis in such a way as to result in an impermissible reduction in taxes under applicable PRC laws, rules and regulations, and adjust the income of the VIEs in the form of a transfer pricing adjustment. A transfer pricing adjustment could, among other things, result in a reduction of expense deductions recorded by the VIEs for PRC tax purposes, which could in turn increase their tax liabilities without reducing the VIEs' tax expenses. In addition, the PRC tax authorities may impose late payment fees and other penalties on the VIEs for the adjusted but unpaid taxes according to the applicable regulations. Our financial position could be materially and adversely affected if the VIEs' tax liabilities increase or if they are required to pay late payment fees and other penalties.

Our exercise of the option to acquire equity ownership and assets of the VIEs may subject us to certain limitation and substantial costs.

Pursuant to the contractual arrangements, PRC Subsidiaries have the exclusive right to purchase all or any part of the equity interests in the VIEs from the respective equity holders at a nominal price, unless relevant government authorities or PRC laws require that another amount should be used as the purchase price, in which case the purchase price shall be the lowest amount under such requirement. The equity transfer may be subject to the approvals from and filings with MOFCOM, the State Administration for Market Regulation (the "SAMR") and/or their local competent branches. In addition, the equity transfer price may be subject to review and tax adjustment by the relevant tax authority. Subject to relevant laws and regulations, the shareholders of the VIEs will pay the equity transfer price they receive to PRC Subsidiaries under the contractual arrangements. The amount to be received by PRC Subsidiaries may also be subject to enterprise income tax, and such tax amounts could be substantial.

We may lose the ability to use and enjoy licenses, approvals and assets held by the VIEs that are material to the operation of certain portions of our business if the VIEs go bankrupt or become subject to a dissolution or liquidation proceeding.

We do not have priority pledges and liens against the assets of the VIEs. If either of the VIEs undergo an involuntary liquidation proceeding, third-party creditors may claim rights to some or all of its assets and we may not have priority against such third-party creditors on the assets of the VIEs. If either of the VIEs liquidates, we may take part in the liquidation procedures as a general creditor under the PRC Enterprise Bankruptcy Law and recover any outstanding liabilities owed by VIEs to PRC Subsidiaries under the applicable service agreement.

If the shareholders of the VIEs were to attempt to voluntarily liquidate the VIEs without obtaining our prior consent, we could effectively prevent such unauthorized voluntary liquidation by exercising our right to request the shareholders of the VIEs to transfer all of their respective equity ownership interests to a PRC entity or individual designated by us in accordance with the option agreement with the shareholders of the VIEs. In addition, under the VIE agreements signed by the VIEs and their shareholders, the shareholders of the VIEs do not have the right to issue dividends to themselves or otherwise distribute the retained earnings or other assets of the VIEs without our consent. Similarly, the shareholders of the VIEs do not have the right to distribute the retained earnings or other assets of the VIEs without our consent. In the event that the shareholders of the VIEs initiate a voluntary liquidation proceeding without our authorization or attempts to distribute the retained earnings or assets of the VIEs without our prior consent, we may need to resort to legal proceedings to enforce the terms of the contractual arrangements. Any such legal proceeding may be costly and may divert our management's time and attention away from the operation of our business, and the outcome of such legal proceeding will be uncertain.

RISKS RELATED TO DOING BUSINESS IN THE PRC

If we fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or our third parties' disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials. This insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous or radioactive materials.

We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

We are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery laws of other jurisdictions, particularly China. Other U.S. listed companies in the life science industry have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. We cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or interpretation thereof. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

We may be subject to additional contributions of social insurance premium and housing provident funds and late payments and fines imposed by relevant governmental authorities.

The SCNPC enacted the PRC Labor Contract Law in 2007 and amended it on December 28, 2012. The Labor Contract Law introduced specific provisions related to fixed-term employment contracts, part-time employment, probationary periods, consultation with labor unions and employee assemblies, employment without a written contract, dismissal of employees, severance, and collective bargaining to enhance previous PRC labor laws. Under the Labor Contract Law, an employer is obligated to sign an unlimited-term labor contract with any employee who has worked for the employer for ten consecutive years. Further, if an employee requests or agrees to renew a fixed-term labor contract that has already been entered into twice consecutively, the resulting contract must have an unlimited term, subject to certain exceptions. With certain exceptions, an employer must pay severance to an employee where a labor contract is terminated or expires. In addition, the PRC governmental authorities have continued to introduce various new labor-related regulations since the effectiveness of the Labor Contract Law.

Under the PRC Social Insurance Law and the Administrative Measures on Housing Provident Funds and other relevant laws and regulations, employees are required to participate in basic pension insurance, work-related injury insurance, basic medical insurance, unemployment insurance, maternity insurance, and housing provident funds (collectively, the "Employee Benefits"). An employer shall pay the Employee Benefits for its employees in accordance with the rates provided under relevant regulations and shall withhold the social insurance and other Employee Benefits that should be assumed by the employees. For example, PRC subsidiaries shall register with local social insurance agencies and register with applicable housing provident funds management centers and establish a special housing provident fund account in an entrusted bank. An employer that has not made social insurance contributions at a rate and based on an amount prescribed by the law, or at all, may be ordered to rectify the non-compliance and pay the required contributions within a stipulated deadline and be subject to a late fee. If the employer still fails to rectify the failure to make social insurance contributions within the stipulated deadline, it may be subject to a fine ranging from one to three times of the amount overdue.

To efficiently administer the contribution to housing provident funds and social insurance in certain cities in China, some of our subsidiaries engage third-party agents to make such contribution for some of our PRC employees. Any failure to make such contribution by these third-party agents may directly expose us to additional contribution, late payment fee and/or penalties imposed by the local authorities and/or legal claims raised by our employees. As of the date of this annual report, we have not received any notice from the relevant government authorities or any claim or request from these employees in this regard. However, we cannot assure you that the relevant government authorities will not require us to pay the outstanding amount and impose late fees or fines on us. If we are otherwise subject to investigations related to non-compliance with labor laws and are imposed severe penalties or incur significant legal fees in connection with labor disputes or investigations, our business, financial condition and results of operations may be adversely affected.

These laws designed to enhance labor protection tend to increase our labor costs. In addition, as the interpretation and implementation of these regulations are still evolving, our employment practices may not be at all times be deemed in compliance with the regulations. As a result, we could be subject to penalties or incur significant liabilities in connection with labor disputes or investigations.

We may be required to obtain approval or complete filing or other requirements of the CSRC or other PRC government authorities in connection with our issuances of securities overseas, and, if required, we cannot predict whether we will be able to obtain such approval or complete such governmental procedure.

The M&A Rules requires an overseas special purpose vehicle formed for listing purposes through acquisitions of PRC domestic companies and controlled by PRC companies or individuals to obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle's securities on an overseas stock exchange. However, the application of the M&A Rules remains unclear. If CSRC approval is required for any of our future offerings of securities overseas or to maintain the listing status of the ADSs, it is uncertain whether it would be possible for us to obtain the approval, and any failure to obtain or delay in obtaining such approval would subject us to sanctions imposed by the CSRC and other PRC government authorities.

We completed our initial public offering on the Nasdaq on June 19, 2020. It is uncertain when and whether we will be required to obtain permission from the PRC government to maintain our listing status on U.S. exchanges in the future, and even when such permission is obtained, whether it will be later denied or rescinded. On December 24, 2021, the CSRC issued the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (collectively, "the Draft Overseas Listing Regulations"), which propose to require PRC companies and their overseas special purpose vehicles to file with the CSRC and meet compliance rules for their listing in overseas markets.

Pursuant to the press conference held by CSRC on December 24, 2021, according to the principle of *lex prospect non respect*, the foresaid requirements in the Draft Overseas Listing Regulations shall be currently applicable to the PRC companies and their overseas special purpose vehicles that seek to offer and list securities in overseas markets only, filing procedures of these already listed in overseas markets shall be arranged separately. These draft regulations were released only for soliciting public comment as of the date of this annual report and their provisions and anticipated adoption or effective date are subject to changes and thus their interpretation and implementation remain substantially uncertain. As a result, we cannot predict their impact on our future offerings of securities overseas, if any, at this stage, or guarantee that we will be able to satisfy the scrutinized and new regulatory requirements in case they were adopted in the current form. As of the date of this annual report, the Draft Overseas Listing Regulations have not been formally adopted, we believe that our company, our PRC subsidiaries, and the VIEs, are currently not required to obtain permission from any Chinese authorities, and none of them has received any notice of denial of permission to list on the U.S. national exchange, we cannot assure you that the relevant PRC government agencies, including the CSRC, would reach the same conclusion as we do. If the CSRC or any other PRC regulatory body subsequently determines that we need to file with the CSRC or obtain the CSRC's approval for any future offering of securities by us or to maintain the listing status of our ADSs, or if the CSRC or any other PRC government authorities promulgates any interpretation or implements rules that would require us to file with or obtain approvals of the CSRC or other governmental bodies for any such offering, we may face adverse actions or sanctions by the CSRC or other PRC regulatory agencies, which may include fines and penalties on our operations in China, limitations on our operating privileges in China, delays in or restrictions on the repatriation of the proceeds from any such offering into the PRC, restrictions on or prohibition of the payments or remittance of dividends by our subsidiaries in China, or other actions that could have a material and adverse effect on our business, reputation, financial condition, results of operations, prospects, as well as the trading price of the ADSs. The CSRC or other PRC regulatory agencies may also take actions requiring us, or making it advisable for us, to halt any such offering before the settlement and delivery of the ADSs that we may offer. Consequently, if you engage in market trading or other activities in anticipation of and prior to the settlement and delivery of the ADSs we offer, you would be doing so at the risk that the settlement and delivery may not occur. In addition, if the CSRC or other regulatory agencies later promulgate new rules or explanations requiring that we file with them, or obtain their approvals or clearances for any such offering or the listing of the ADSs, we may be unable to obtain a waiver of such regulatory requirements. Any uncertainties and/or negative publicity regarding such an approval or other requirements could have a material adverse effect on the trading price of the ADSs.

In addition, 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” (“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 supervision on overseas listings by China-based companies. These Opinions proposed to take effective measures, such as promoting the construction of relevant regulatory systems, to deal with the risks and incidents facing China-based overseas-listed companies and the demand for cybersecurity and data privacy protection. The policies described above and any related implementation rules to be enacted may subject us to additional compliance requirement in the future. As the Opinions were recently issued, official guidance to act upon, and interpretation of the Opinions, remain unclear in several respects at this time. Therefore, we cannot assure you that we will remain fully compliant with all new regulatory requirements of the Opinions or any future implementation rules on a timely basis, or at all.

Uncertainties with respect to the PRC legal system, including uncertainties regarding the enforcement of laws, and changes in laws, regulations and policies in China could adversely affect us.

Our operations in China are governed by the PRC laws and regulations. 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. Since the PRC legal system continues to rapidly evolve, the interpretations of many laws and regulations are not always uniform and enforcement of these laws and regulations involves uncertainties. In addition, any new PRC laws or changes in PRC laws and regulations related to, among other things, foreign investment and manufacturing in China could have a material adverse effect on our business and our ability to operate our business in China.

From time to time, we may have to resort to administrative and court proceedings to enforce our legal rights. Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory provisions and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy, than in more developed legal systems. These uncertainties may impede our ability to enforce contracts in China and could materially and adversely affect our business and results of operations.

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 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. Such unpredictability towards our contractual, property and procedural rights and any failure to quickly respond to changes in the regulatory environment in the PRC could adversely affect our business, and impede our ability to continue our operations and proceed with our future business plans.

PRC government has significant oversight over the conduct of our business.

PRC government has significant oversight over the conduct of our business and may intervene in our operations as the government deems appropriate, which may potentially result in a material adverse effect on our operations. PRC government has also recently indicated an intent to exert more oversight over offerings that are conducted overseas and foreign investment in China-based issuers, which could impact our ability to raise additional capital in international capital markets. In addition, the PRC government has recently published new policies that significantly affected certain industries, and we cannot rule out the possibility that it will in the future release regulations or policies regarding our industry that could adversely affect our business, financial condition and results of operations. Any such action could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of our securities to significantly decline or be worthless.

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

Genetron Holdings Limited is a holding company incorporated under the laws of the Cayman Islands with no operations of its own. It conducts substantially all of its operations in China primarily through its VIEs and subsidiaries of such VIEs, and substantially all of its assets are located in China. As such, investors in the ADSs of Genetron Holdings Limited are not purchasing equity securities of its subsidiaries that have substantive business operations in China but instead are purchasing equity securities of a Cayman Islands holding company. In addition, all our senior executive officers and directors are located outside of the Cayman Islands, they reside within China for a significant portion of the time and most are PRC nationals. Service of court documents on a Cayman Islands company can be effected by serving the documents at the company's registered office and it may be possible to enforce foreign judgments in the Cayman Islands against a Cayman Islands company, subject to some exceptions. However, if investors wish to serve documents on and/or enforce foreign judgments against our directors and officers, they will need to ensure that they comply with the rules of the jurisdiction where the directors and officers are located. As a result, it may be difficult for our shareholders or ADS holders to effect service of process upon us, depending on where our officers and directors are located. In addition, China 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 China 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.

Shareholder claims that are common in the United States, including securities law class actions and fraud claims, generally are difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to obtaining information needed for shareholder investigations or litigation outside China or otherwise with respect to foreign entities. Although the local authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such regulatory cooperation with the securities regulatory authorities in the United States have not been efficient in the absence of mutual and practical cooperation mechanism.

In addition, according to Article 177 of the PRC Securities Law which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no organization or individual may provide the documents and materials related to securities business activities to overseas parties.

Substantial uncertainties exist with respect to the interpretation and implementation of Foreign Investment Law and how it may impact the viability of our current corporate structure, corporate governance and business operations.

On March 15, 2019, the PRC National People's Congress approved the PRC Foreign Investment Law, which came into effect on January 1, 2020 and replaces the trio of existing laws regulating foreign investment in the PRC, namely, the PRC Sino-Foreign Equity Joint Venture Enterprise Law, the PRC Sino-Foreign Cooperative Joint Venture Enterprise Law and the PRC Wholly Foreign-Invested Enterprise Law, and become the legal foundation for foreign investment in the PRC. Meanwhile, the PRC Implementation Regulation of the Foreign Investment Law came into effect as of January 1, 2020, which clarified and elaborated the relevant provisions of the Foreign Investment Law.

The Foreign Investment Law sets out the basic regulatory framework for foreign investments and proposes to implement a system of pre-entry national treatment with a negative list for foreign investments, pursuant to which (i) foreign entities and individuals are prohibited from investing in the areas that are not open to foreign investments, (ii) foreign investments in the restricted industries must satisfy certain requirements under the law, and (iii) foreign investments in business sectors outside of the negative list will be treated equally with domestic investments. The Foreign Investment Law also sets forth necessary mechanisms to facilitate, protect and manage foreign investments and proposes to establish a foreign investment information reporting system, through which foreign investors are required to submit information related to their investments to MOFCOM or its local branches.

However, since it is relatively new, uncertainties still exist in relation to its interpretation and implementation. For example, the Foreign Investment Law of the PRC adds a catch-all clause to the definition of “foreign investment” so that foreign investment, by its definition, includes “investments made by foreign investors in China through other means defined by other laws or administrative regulations or provisions promulgated by the State Council” without further elaboration on the meaning of “other means.” The Implementing Regulation of the Foreign Investment Law Regulations, or the FIL Interpretations, adopted by the State Council on December 12, 2019 also did not provide further clarification for such “other means.” The most updated negative list, issued on December 27, 2021 and became effective on January 1, 2022, stipulates that any PRC domestic enterprise engaging in prohibited industries under the negative list shall obtain the consent of the relevant competent PRC authorities for overseas listing, and the foreign investors shall not participate in the operation and management of such enterprise, and the shareholding percentage of the foreign investors in such enterprise shall be subject to the relevant administrative provisions of the PRC domestic securities investment by foreign investors. Such negative list does not further elaborate whether existing overseas listed enterprises like us will be subject to such requirements. Further, pursuant to the press conference held by the NDRC on January 18, 2022, the requirements described above will not be applicable to the domestic enterprises that seek to offer and list securities in overseas markets indirectly.

Though it does not explicitly classify contractual arrangements as a form of foreign investment, there is no assurance that foreign investment via contractual arrangement would not be interpreted as a type of indirect foreign investment activities under the definition in the future. Furthermore, if future legislations prescribed by the State Council mandate further actions to be taken by companies with respect to existing contractual arrangements, we may face substantial uncertainties as to whether we can complete such actions in a timely manner, or at all. If we fail to take appropriate and timely measures to comply with any of these or similar regulatory compliance requirements, our current corporate structure, corporate governance and business operations could be materially and adversely affected. In the extreme case-scenario, we may be forced to unwind the contractual arrangements and/or dispose of the VIEs, which could have a material and adverse effect on our business, financial condition and result of operations.

For details of the Foreign Investment Law and the Negative List and its potential impact on our Company, see “Item 4. Organizational Structure—4.C. Organization Structure—Contractual Arrangements with the VIEs and their Shareholders.”

Any non-compliance with PRC advertising laws and regulations by us may subject us to penalties.

We are obligated to ensure our advertising content to comply with applicable laws. For example, no medical advertisements or medical device advertisements shall be published before relevant approval has been obtained from competent government authority. Please see “Item 4. Information on the Company—4.B. Business Overview—Regulations—PRC Regulations—Regulations related to Advertisement.” Any violation of the relevant laws and regulations may subject us to governmental penalties, impair our brand and adversely impact our financial condition and results of operations.

The lease agreements of our leased properties have not been registered with the relevant PRC government authorities as required by PRC law, which may expose us to potential fines.

Under PRC law, lease agreements of commodity housing tenancy are required to be registered with the local construction (real estate) departments. Although failure to do so does not in itself invalidate the leases, the parties of the lease agreements may be exposed to potential fines if they fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the date of this annual report, the lease agreements for all of our leased properties in China, including leased properties for our spaces, had not been registered with the relevant PRC government authorities. As of the date of this annual report, we had not been aware of any regulatory or governmental actions, claims or investigations being contemplated or any challenges by third parties to our use of our leased properties, or the lease agreements of which had not been registered with the government authorities. However, we cannot assure you that the government authorities will not impose fines on us due to our failure to register any of our lease agreements, which may negatively impact our financial condition.

Our rights to use our leased properties could be challenged by property owners or other third parties, which may disrupt our operations and incur relocation costs.

As of the date of this annual report, we had a number of title defects with respect to some of our leased properties, for example, the lessors of certain of our leased properties in China had failed to provide us with valid property ownership certificates or authorizations from the property owners for the lessors to sublease the properties. If such lessors do not have the relevant property ownership certificates or the right to lease or sublease such properties to us, the relevant rightful title holders or other third parties may challenge our use of such leased properties, and we may be forced to vacate these properties and be required to seek alternative properties for lease. In such an event, our business operations will be interrupted, and relocation costs will be incurred. Moreover, if our lease agreements are challenged by third parties, it could result in diversion of management attention and cause us to incur costs associated with defending such actions, even if such challenges are ultimately determined in our favor.

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.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Equity Incentive Plans of Overseas Listed Companies, replacing earlier rules promulgated in 2007. Pursuant to these rules, PRC citizens and non-PRC citizens who reside in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiaries 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 and transfer of relevant funds. We and our executive officers and other employees who are PRC citizens or who reside in the PRC for a continuous period of not less than one year and who have been granted options will be subject to these regulations. Failure to complete SAFE registrations may subject them to fines and legal sanctions, there may be additional restrictions on the ability of them to exercise their stock options or remit proceeds gained from the sale of their stock into the PRC. We also face regulatory uncertainties that could restrict our ability to adopt incentive plans for our directors, executive officers and employees under PRC law. See “Item 4. Information on the Company—4.B. Business Overview—Regulation—Regulations Related to Foreign Exchange—Share Option Rules.”

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 or ADS holders.

Under the PRC Enterprise Income Tax Law, and its implementation rules, an enterprise established outside of 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 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 over and overall management of the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State Administration of Taxation (the “SAT”) issued the Circular on Issues Concerning the Identification of Chinese-Controlled Organizational Management, 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 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 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 and the places where the senior executives and the senior management department perform their duties are in the PRC; (ii) decisions related 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 minutes and files of board meetings and shareholder meetings, 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 that we are not a PRC resident enterprise for PRC tax purposes. See “Item 10. Additional Information—10.E. Taxation—PRC Taxation.” 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 we are a PRC resident enterprise for enterprise income tax purposes, we will be subject to a 25% tax on our worldwide income. In addition, we may be required to withhold a 10% withholding tax from dividends we pay to our shareholders that are non-resident enterprises, including the holders of the ADSs. In addition, non-resident enterprise shareholders (including ADS holders) may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within the PRC. Furthermore, if we are deemed a PRC resident enterprise, dividends payable to our non-PRC individual shareholders (including ADS holders) and any gain realized on the transfer of ADSs or 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). Any PRC tax liability may be reduced under applicable tax treaties. However, it is unclear whether in practice our non-PRC shareholders would be able to obtain the benefits of any tax treaties between their countries 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 the ADSs or our ordinary shares.

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

Pursuant to the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises (“SAT Circular 698”), issued by the SAT in 2009 with retroactive effect from January 1, 2008, where a non-resident enterprise transfers the equity interests of a PRC resident enterprise indirectly by disposition of the equity interests of an overseas holding company (“Indirect Transfer”), and such overseas holding company is located in a tax jurisdiction that: (i) has an effective tax rate less than 12.5% or (ii) does not tax foreign income of its residents, the non-resident enterprise, being the transferor, shall report to the competent tax authority of the PRC resident enterprise this Indirect Transfer.

On February 3, 2015, the SAT issued the Public Notice Regarding Certain Enterprise Income Tax Matters on Indirect Transfer of Properties by Non-Resident Enterprises (“SAT Bulletin 7”). SAT Bulletin 7 supersedes the rules with respect to the Indirect Transfer under SAT Circular 698. SAT Bulletin 7 has introduced a new tax regime that is significantly different from the previous one under SAT Circular 698. SAT Bulletin 7 extends the PRC’s tax jurisdiction to not only Indirect Transfers set forth under SAT Circular 698 but also transactions involving a transfer of other taxable assets through an offshore transfer of a foreign intermediate holding company. In addition, SAT Bulletin 7 provides clearer criteria than SAT Circular 698 for assessment of reasonable commercial purposes and has introduced safe harbors for internal group restructurings and the purchase and sale of equity securities through a public securities market. SAT Bulletin 7 also brings challenges to both foreign transferor and transferee (or another person who is obligated to pay for the transfer) of taxable assets. 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, being the transferor, or the 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 another person who is obligated to pay 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.

On October 17, 2017, the SAT issued the Announcement on Issues Concerning the Withholding of Non-resident Enterprises Income Tax at Source (“SAT Bulletin 37”), which, among others, repealed the SAT Circular 698 on December 1, 2017. SAT Bulletin 37 further details and clarifies the tax withholding methods in respect of income of non-resident enterprises under SAT Circular 698. Certain rules stipulated in SAT Bulletin 7 are replaced by SAT Bulletin 37. Where the non-resident enterprise fails to declare the tax payable pursuant to Article 39 of the PRC Enterprise Income Tax Law, the tax authority may order it to pay the tax due within required time limits, and the non-resident enterprise shall declare and pay the tax payable within such time limits specified by the tax authority; however, if the non-resident enterprise voluntarily declares and pays the tax payable before the tax authority orders it to do so within required time limits, it shall be deemed that such enterprise has paid the tax in time.

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 a transferor in such transactions, and may be subject to withholding obligations if our Company is a transferee in such transactions, under SAT Bulletin 7 and 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 SAT Bulletin 37. As a result, we may be required to expend valuable resources to comply with SAT Bulletin 7 and 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.

If our preferential tax treatments are revoked, become unavailable or if the calculation of our tax liability is successfully challenged by the PRC tax authorities, we may be required to pay tax, interest and penalties in excess of our tax provisions, and our results of operations could be materially and adversely affected.

The Chinese government has provided various tax incentives to our subsidiaries in China. These incentives include reduced enterprise income tax rates. For example, under the PRC Enterprise Income Tax Law and its implementation rules, the statutory enterprise income tax rate is 25%. However, the income tax of an enterprise that has been determined to be a National High-Tech Enterprise can be reduced to a preferential rate of 15%. Any increase in the enterprise income tax rate applicable to our PRC Subsidiaries in China, or any discontinuation or retroactive or future reduction of any of the preferential tax treatments currently enjoyed by the VIEs in China, could adversely affect our business, financial condition and results of operations. In addition, in the ordinary course of our business, we are subject to complex income tax and other tax regulations and significant judgment is required in the determination of a provision for income taxes. Although we believe our tax provisions are reasonable, if the PRC tax authorities successfully challenge our position and we are required to pay tax, interest and penalties in excess of our tax provisions, our financial condition and results of operations would be materially and adversely affected.

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”), adopted by six PRC regulatory agencies in 2006 and amended in 2009, 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 MOFCOM 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 on Thresholds for Prior Notification of Concentrations of Undertakings, issued by the State Council in 2008 and amended in 2018, were triggered. Moreover, the Anti-Monopoly Law of the PRC promulgated by the SCNPC, which became effective in 2008 requires that transactions which are deemed concentrations and involve parties with specified turnover thresholds must be cleared by MOFCOM before they can be completed. In addition, Provisions of the Ministry of Commerce on the Implementation of the Security Review System for Mergers and Acquisitions of Domestic Enterprises by Foreign Investors which became effective in September 2011 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. Furthermore, according to the Measures for the Security Review of Foreign Investment, or the New Security Review Measures, promulgated by the NDRC and MOFCOM on December 19, 2020, a foreign investment security review working mechanism will be established to be responsible for organizing, coordinating and guiding the security review of foreign investment. If a proposed foreign investment meets the conditions as stipulated in the New Security Review Measures, the foreign investor or the relevant domestic party shall report such case to the review working mechanism authority, in order to obtain the security review clearance before proceeding with the proposed foreign investment. However, as the New Security Review Measures was newly issued, there are still substantial uncertainties as to its interpretation and implementations in practice. 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 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 related 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 Administration on Domestic Residents’ Overseas Investment, Financing and Roundtrip Investment via Special Purpose Vehicles (“SAFE Circular 37”). SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purpose 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, SAFE promulgated the Notice on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (“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.

We have requested PRC residents who we know hold direct or indirect interest in our Company to make the necessary applications, filings and registrations as required under SAFE Circular 37 and those PRC resident shareholders that hold direct interest in our Company have completed all necessary registrations with the local SAFE branch or qualified banks as required by SAFE Circular 37. However, we may not be informed of the identities of all the PRC residents holding direct or indirect interest in our Company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our PRC resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, restrict our cross-border investment activities, limit the ability of our PRC Subsidiaries to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into the subsidiary. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

Furthermore, as these foreign exchange regulations are still relatively new and their interpretation and implementation has 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.

PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of our initial public offering 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.

We are an offshore holding company conducting our operations in China through our PRC Subsidiaries and VIEs. We may make loans to our PRC Subsidiaries and VIEs subject to the approval or registration from governmental authorities and limitation of amount, or we may make additional capital contributions to our PRC Subsidiaries. Any loans to our PRC Subsidiaries, which are treated as foreign invested enterprises under PRC law, are subject to foreign exchange loan registrations. In addition, a foreign invested enterprise shall use its capital pursuant to the principle of authenticity and self-use within its business scope. The capital of a foreign invested enterprise shall not be used for the following purposes: (i) directly or indirectly used for payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities or investments other than banks' principal-secured products unless otherwise provided by relevant laws and regulations; (iii) the granting of loans to non-affiliated enterprises, except where it is expressly permitted in the business license; and (iv) paying the expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans by us to our PRC Subsidiaries or VIEs or with respect to future capital contributions by us to our PRC Subsidiaries. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds from our initial public offering and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

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 are a Cayman Islands holding company and we rely principally on dividends and other distributions on equity from our PRC Subsidiaries for our cash requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders for services of any debt we may incur. 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 distributions to us. Under PRC laws and regulations, our PRC Subsidiaries, which are foreign invested enterprises, may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, foreign invested enterprises are required to set aside at least 10% of their accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of their registered capital. Such reserve funds cannot be distributed to us as dividends. At their discretion, foreign invested enterprises may allocate a portion of their after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund.

Our PRC Subsidiaries generate primarily all of their revenue in RMB, which is not freely convertible into other currencies. As a result, any restriction on currency exchange may limit the ability of our PRC Subsidiaries to use their RMB revenues to pay dividends to us.

The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC Subsidiaries to pay dividends or make other kinds of payments to us 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.

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

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions in China and by China's foreign exchange policies. Since June 2010, the RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably. Since October 1, 2016, RMB has joined the International Monetary Fund's basket of currencies that make up the Special Drawing Right along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016 the RMB has depreciated significantly in the backdrop of a surging U.S. dollar and persistent capital outflows of China. With the development of the foreign exchange market and progress towards interest rate liberalization and RMB internationalization, the PRC government may in the future announce further changes to the exchange rate system, and we cannot assure you that the RMB will not appreciate or depreciate significantly in value against the U.S. dollar in the future. 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.

There remains significant international pressure on the Chinese government to adopt a flexible currency policy to allow the RMB to appreciate against the U.S. dollar. Significant revaluation of the RMB may have a material adverse effect on your investment. Substantially all of our revenues and expenses are denominated in RMB. Any significant revaluation of RMB may adversely affect our revenues, earnings and financial position, and the value of, and any dividends payable on the ADSs in U.S. dollars. To the extent that we need to convert U.S. dollars into RMB for capital expenditures and working capital and other business purposes, appreciation of RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, a significant depreciation of RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our earnings, which in turn could adversely affect the price of the ADSs, and if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on the ADSs, strategic acquisitions or investments or other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount available to us.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert RMB into foreign currency. As a result, fluctuations in exchange rates may have a material adverse effect on your investment.

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

The PRC government imposes controls on the convertibility of the RMB into foreign currencies and, in certain cases, the remittance of currency out of China. We receive substantially all of our revenues in RMB. Under our current corporate structure, our Cayman Islands holding company primarily relies 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 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 the cash generated from the operations of our PRC Subsidiaries and VIEs to pay off their respective debt in a currency other than RMB owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than RMB. 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 ADSs.

The PCAOB is currently unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections over our auditor deprives our investors with the benefits of such inspections.

Our auditor, the independent registered public accounting firm that issues the audit report included elsewhere in this annual report, as an auditor of companies that are traded publicly in the United States and a firm registered with the Public Company Accounting Oversight Board (United States) (the “PCAOB”), is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. Since our auditor is located in China, a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the Chinese authorities, our auditor is not currently inspected by the PCAOB.

This lack of the PCAOB inspections in China prevents the PCAOB from fully evaluating audits and quality control procedures of our independent registered public accounting firm. As a result, we and investors in our ordinary shares and/or ADS are deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our independent registered public accounting firm’s audit procedures or quality control procedures as compared to auditors outside of China that are subject to the PCAOB inspections, which could cause investors and potential investors in our ordinary shares and/or ADSs to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

Trading in our ADSs on the Nasdaq Stock Market or in the over-the-counter market will be prohibited, and as a result, our ADSs will be delisted under the HFCA Act, if the PCAOB is unable to inspect or fully investigate auditors located in China. On December 16, 2021, the PCAOB issued the HFCA Act Determination Report, according to which our auditor is subject to the determinations that the PCAOB is unable to inspect or investigate completely. The delisting of our ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment. If this happens there is no certainty that we will be able to list our ordinary shares on a non-U.S. exchange or that a market for our ordinary shares will develop outside of the United States.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, the Holding Foreign Companies Accountable Act (the "HFCA Act"), has been signed into law on December 18, 2020. The HFCA Act requires the SEC to prohibit the trading of securities of a Chinese or a non-U.S. company on U.S. securities exchanges or the over-the-counter market if the PCAOB has determined that it has been unable to inspect the company's accounting firm for three consecutive years because of a position taken by an authority in the company's jurisdiction. The HFCA Act also requires such companies to make certain disclosures about their ownership by governmental entities and their relationships with the Chinese Communist Party.

On December 2, 2021, the SEC adopted final amendments to its rules implementing the HFCA Act (the "Final Amendments"). The Final Amendments finalize the interim final rules adopted in March with two major modifications. First, the Final Amendments clarify how the requirements apply to variable interest entities. Second, the Final Amendments include requirements to disclose information, including the auditor name and location, the percentage of shares of the issuer owned by governmental entities, whether governmental entities in the applicable foreign jurisdiction with respect to the auditor has a controlling financial interest with respect to the issuer, the name of each official of the Chinese Communist Party who is a member of the board of the issuer, and whether the articles of incorporation of the issuer contains any charter of the Chinese Communist Party. The Final Amendments also establish procedures the SEC will follow in identifying issuers and prohibiting trading by certain issuers under the HFCA Act.

On December 16, 2021, PCAOB issued the HFCA Act Determination Report, according to which our auditor is subject to the determinations that the PCAOB is unable to inspect or investigate completely. In March 2022, the SEC issued its first "Conclusive list of issuers identified under the HFCAA" indicating that those companies are now formally subject to the delisting provisions if they remain on the list for three consecutive years. We anticipate being added to the list shortly after the filing of this annual report on Form 20-F.

The HFCA Act or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of the ADSs could be adversely affected. Additionally, whether the PCAOB will be able to conduct inspections of our auditor in the three consecutive years or at all, is subject to substantial uncertainty and depends on factors out of our and our auditor's control. If our auditor is unable to meet the PCAOB inspection requirement in time, we will be delisted from the Nasdaq and our ADSs will not be permitted for trading over-the-counter either. Such a delisting would substantially impair your ability to sell or purchase our ADSs when you wish to do so, and the risk and uncertainty associated with delisting would have a negative impact on the price of our ADSs.

If our ADS are delisted from the U.S. securities exchange and are prohibited from trading in the over-the-counter market in the United States, there is no certainty that we will be able to list our ordinary shares on a non U.S. securities exchange or that a market for our ordinary shares will develop outside of the United States. Such a delisting would significantly affect our ability to raise capital on terms acceptable to us, or at all, which would have a material adverse impact on our business, financial condition and prospects.

The potential enactment of the Accelerating Holding Foreign Companies Accountable Act would decrease the number of non-inspection years from three years to two, thus reducing the time period before our ADSs may be prohibited from trading on the Nasdaq Stock Market or in the over-the-counter market or delisted.

On June 22, 2021, the U.S. Senate passed a bill, also known as the Accelerating Holding Foreign Companies Accountable Act, to amend Section 104(i) of the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7214(i)) to prohibit securities of any registrant from being listed on any of the U.S. securities exchanges or traded over-the-counter if the auditor of the registrant's financial statements is not subject to PCAOB inspection for two consecutive years, instead of three consecutive years as currently required under the HFCA Act, after the law becomes effective. On February 4, 2022, the U.S. House of Representatives passed the America COMPETES Act of 2022, which includes the exact same amendments as the bill passed by the Senate. The America COMPETES Act of 2022 however includes a broader range of legislation not related to the HFCA Act in response to the U.S. Innovation and Competition Act passed by the Senate in 2021. The U.S. House of Representatives and U.S. Senate will need to agree on amendments to these respective bills to align the legislation and pass their amended bills before the President can sign into law. It is unclear when the U.S. Senate and U.S. House of Representatives will resolve the differences in the U.S. Innovation and Competition Act and the America COMPETES Act of 2022 bills currently passed, or when the U.S. President will sign on the bill to make the amendment into law, or at all. In the case that the bill becomes the law, it will reduce the time period before our ADSs may be prohibited from trading on the Nasdaq Stock Market or in the over-the-counter market or be delisted.

Proceedings instituted by the SEC against four PRC-based accounting firms, including our independent registered public accounting firm, could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act.

Starting in 2011 the China-based “big four” accounting firms, including our independent registered public accounting firm, were affected by a conflict between U.S. and PRC law. Specifically, for certain U.S.-listed companies operating and audited in mainland China, the SEC and the PCAOB sought to obtain from the Chinese firms access to their audit work papers and related documents. The firms were, however, advised and directed that under PRC law, they could not respond directly to the U.S. regulators on those requests, and that requests by foreign regulators for access to such papers in China had to be channeled through the CSRC.

In late 2012, this impasse led the SEC to commence administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the Chinese accounting firms, including our independent registered public accounting firm. A first instance trial of the proceedings in July 2013 in the SEC's internal administrative court resulted in an adverse judgment against the firms. The administrative law judge proposed penalties on the firms including a temporary suspension of their right to practice before the SEC, although that proposed penalty did not take effect pending review by the Commissioners of the SEC. On February 6, 2015, before a review by the Commissioners had taken place, the firms reached a settlement with the SEC. Under the settlement, the SEC accepted that future requests by the SEC for the production of documents will normally be made to the CSRC. The firms were to receive matching Section 106 requests, and were required to abide by a detailed set of procedures with respect to such requests, which in substance require them to facilitate production via the CSRC. If they failed to meet specified criteria, the SEC retained authority to impose a variety of additional remedial measures on the firms depending on the nature of the failure. Under the terms of the settlement, the underlying proceeding against the four PRC-based accounting firms was deemed dismissed with prejudice at the end of four years starting from the settlement date, which was February 6, 2019. We cannot predict if the SEC will further challenge the four PRC-based accounting firms' compliance with U.S. law in connection with U.S. regulatory requests for audit work papers or if the results of such a challenge would result in the SEC imposing penalties such as suspensions. If additional remedial measures are imposed on the China-based “big four” accounting firms, we could be unable to timely file future financial statements in compliance with the requirements of the Exchange Act.

In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about any such future proceedings against these audit firms may cause investor uncertainty regarding China-based, U.S.-listed companies and the market price of our securities may be adversely affected.

If our independent registered public accounting firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to the delisting of the ADSs from the Nasdaq or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of the ADSs in the United States.

RISKS RELATED TO THE AMERICAN DEPOSITARY SHARES

Our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ADSs, may be adversely affected by the geopolitical factors arising in connection with the military operation of Russia in Ukraine, including particularly how countries like the United States and China choose to respond to the ongoing military conflict. As a result, the value of our ADSs may significantly decline.

Our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ADSs, may be adversely affected by the geopolitical factors arising in connection with the military operation of Russia in Ukraine. We do not conduct business in either Russia or Ukraine. However, our global operations expose us to geopolitical risks, including particularly here, how the United States and China choose to respond to the ongoing military conflict between Russia and Ukraine. If this war continues, increases, or expands, or leads to continued political or economic instability, terrorist activity, or gives rise to further government actions such as sanctions or increased economic or political tensions between the United States and China, our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ADSs, may be adversely impacted and the value of our ADSs may significantly decline.

The trading price of the ADSs is likely to be volatile, which could result in substantial losses to investors.

The trading price of the ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. The closing price of the ADSs ranged from US\$1.70 to US\$30.64 per ADS since the listing of ADSs on Nasdaq to the date of this annual report. This may happen because of broad market and industry factors, including the performance and fluctuation of the market prices of other companies with business operations located mainly in China that have listed their securities in the United States. In addition to market and industry factors, the price and trading volume for the ADSs may be highly volatile for factors specific to our own operations, including the following:

- variations in our net revenues, earnings and cash flow;
- announcements of new investments, acquisitions, strategic partnerships, or joint ventures by us or our competitors;
- announcements of new products and services and expansions by us or our competitors;
- changes in financial estimates by securities analysts;
- fluctuations in operating metrics;
- failure on our part to realize monetization opportunities as expected;
- changes in revenues generated from our significant business partners;
- additions or departures of key personnel;
- release of lock-up or other transfer restrictions on our outstanding equity securities or sales or perceived sales of additional equity securities;
- detrimental negative publicity about us, our management, our competitors or our industry;
- a lack of effective internal control over financial reporting;

- inadequate corporate governance policies, or allegations of fraud, among other things, involving China-based issuers;
- regulatory developments affecting us or our industry; and
- potential litigation or regulatory investigations.

Any of these factors may result in large and sudden changes in the trading volume and price of the ADSs.

In the past, shareholders of public companies have often brought securities class action suits against those companies following periods of instability in the market price of their securities. If we were involved in a class action suit, it could divert a significant amount of our management's attention and other resources from our business and operations and require us to incur significant expenses to defend the suit, which could harm our results of operations. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages, which could have a material adverse effect on our financial condition and results of operations.

Litigation and negative publicity surrounding China-based companies listed in the U.S. may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs and could have a material adverse effect upon our business, results of operations, financial condition and prospects.

We believe that litigation and negative publicity surrounding companies with operations in China that are listed in the U.S. have negatively impacted stock prices for such companies. Various equity-based research organizations have published reports on China-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in the ADS trading price, and increased directors and officers insurance premiums, and could have a material adverse effect upon our business, results of operations and financial condition.

If securities or industry analysts cease to publish research or reports about our business, or if they adversely change their recommendations regarding the ADSs, the market price for the ADSs and trading volume could decline.

The trading market for the ADSs will be influenced by research or reports that industry or securities analysts publish about our business. If one or more analysts who cover us downgrade the ADSs, the market price for the ADSs 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 the ADSs to decline.

The sale or availability for sale, or perceived sale or availability for sale, of substantial amounts of the ADSs could adversely affect their market price.

Sales of substantial amounts of the ADSs in the public market, or the perception that these sales could occur, could adversely affect the market price of the ADSs and could materially impair our ability to raise capital through equity offerings in the future. The ADSs sold in our initial public offering are freely tradable by persons other than our "affiliates" without restriction or further registration under the Securities Act, and shares held by our existing shareholders may also be sold in the public market subject to the restrictions in Rule 144 and Rule 701 under the Securities Act and the applicable lock-up agreements. Certain major holders of our ordinary shares have the right to cause us to register under the Securities Act the sale of their shares, subject to the applicable Lock-up Period in connection with our initial public offering. Registration of these shares under the Securities Act would result in ADSs representing these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. Sales of these registered shares in the form of ADSs in the public market could cause the price of our ADSs to decline significantly.

The voting rights of holders of ADSs are limited by the terms of the deposit agreement, and you may not be able to exercise your right to vote the underlying ordinary shares represented by your ADSs.

Holders of ADSs do not have the same rights as our registered shareholders. As a holder of ADSs, you will not have any direct right to attend general meetings of our shareholders or to cast any votes at such meetings. You will only be able to exercise the voting rights which are carried by the underlying ordinary shares represented by your ADSs indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. If we instruct the depositary to solicit voting instructions, then upon receipt of your voting instructions, the depositary will try, as far as is practicable, to vote the underlying ordinary shares represented by your ADSs in accordance with your instructions. If we do not instruct the depositary to ask for your instructions, the depositary may still vote in accordance with the instructions you give, but it is not required to do so. You will not be able to directly exercise your right to vote with respect to the underlying ordinary shares unless you cancel your ADSs and withdraw the shares, and become the registered holder of such shares prior to the record date for the general meeting. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to withdraw the ordinary shares represented by your ADSs and become the registered holder of such shares to allow you to attend the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. In addition, under our memorandum and articles of association, for the purposes of determining those shareholders who are entitled to attend and vote at any general meeting, our directors may close our register of members and/or fix in advance a record date for such meeting, and such closure of our register of members or the setting of such a record date may prevent you from withdrawing the underlying ordinary shares represented by your ADSs and becoming the registered holder of such shares prior to the record date, so that you would not be able to attend the general meeting or to vote directly. If we ask for your instructions, the depositary will notify you of the upcoming vote and will arrange to deliver our voting materials to you. If we will instruct the depositary to solicit voting instructions, we will give the depositary at least 30 days' prior notice of shareholder meetings. Nevertheless, we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the underlying ordinary shares represented by your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to direct how the underlying ordinary shares represented by your ADSs are voted and you may have no legal remedy if the underlying ordinary shares represented by your ADSs are not voted as you requested. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

We are entitled to amend the deposit agreement and to change the rights of ADS holders under the terms of such agreement, or to terminate the deposit agreement, without the prior consent of the ADS holders.

We are entitled to amend the deposit agreement and to change the rights of the ADS holders under the terms of such agreement, without the prior consent of the ADS holders. We and the depositary may agree to amend the deposit agreement in any way we decide is necessary or advantageous to us. Amendments may reflect, among other things, operational changes in the ADS program, legal developments affecting ADSs or changes in the terms of our business relationship with the depositary. In the event that the terms of an amendment prejudice a substantial existing right of ADS holders, ADS holders will only receive 30 days' advance notice of the amendment, and no prior consent of the ADS holders is required under the deposit agreement. Furthermore, we may decide to terminate the ADS facility at any time for any reason. For example, terminations may occur when we decide to list our shares on a non-U.S. securities exchange and determine not to continue to sponsor an ADS facility or when we become the subject of a takeover or a going-private transaction. If the ADS facility will terminate, ADS holders will receive at least 90 days' prior notice, but no prior consent is required from them. Under the circumstances that we decide to make an amendment to the deposit agreement that may prejudice a substantial existing right of ADS holders or terminate the deposit agreement, the ADS holders may choose to sell their ADSs or surrender their ADSs and become direct holders of the underlying ordinary shares, but will have no right to any compensation whatsoever.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

Your rights to pursue claims against us and the depositary as a holder of ADSs are limited by the terms of the deposit agreement.

The deposit agreement governing the ADSs representing our ordinary shares provides that ADS holders and the depositary have the right to elect to have any claim they may have against us arising out of or relating to our ordinary shares or ADSs or the deposit agreement settled by arbitration in New York, New York rather than in a court of law, and to have any judgment rendered by the arbitrators entered in any court having jurisdiction. An arbitral tribunal in any such arbitration would not have the authority to award any consequential, special, or punitive damages and its award would have to conform to the provisions of the deposit agreement. The deposit agreement does not give us the right to require that any claim, whether brought by us or against us, be arbitrated.

The deposit agreement also provides that, subject to the claimant's right to require a claim to be submitted to arbitration, the federal or state courts in the State of New York have jurisdiction to hear and determine claims arising under the deposit agreement, our ordinary shares and the ADSs and the transactions contemplated thereby, including any claim under the U.S. federal securities laws. No condition or provision of the deposit agreement or ADSs serves as a waiver by any owner or holder of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder. Therefore, to the extent there are specific federal securities law violation aspects to any claims against us or the depositary brought by any holder or owner of ADSs, the federal securities law violation aspects of such claims may, at the option of such holders or owners, remain in state or federal court in the State of New York. We believe that an optional contractual arbitration provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement.

By agreeing to such optional arbitration provision, you will not be deemed to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ADSs 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 the ADSs as a source for any future dividend income.

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

You may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The depositary has agreed to distribute to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933 but that are not properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not feasible to distribute certain property. Additionally, the value of certain distributions may be less than the cost of distributing them. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

Techniques employed by short sellers may drive down the trading price of the ADSs.

Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller’s interest for the price of the security to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a security short. These short attacks have, in the past, led to selling of shares in the market.

Public companies listed in the United States that have substantially all of their operations in China have been the subject of short selling. Much of the scrutiny and negative publicity has centered on allegations of a lack of effective internal control over financial reporting resulting in financial and accounting irregularities and mistakes, inadequate corporate governance policies or a lack of adherence thereto and, in many cases, allegations of fraud. As a result, many of these companies are now conducting internal and external investigations into the allegations and, in the interim, are subject to shareholder lawsuits and/or SEC enforcement actions.

It is not clear what effect such negative publicity could have on us. If we were to become the subject of any unfavorable allegations, whether such allegations are proven to be true or untrue, we could have to expend a significant amount of resources to investigate such allegations and/or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by principles of freedom of speech, applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming and could distract our management from growing our business. Even if such allegations are ultimately proven to be groundless, allegations against us could severely impact our business operations and stockholder’s equity, and any investment in the ADSs could be greatly reduced or rendered worthless.

You may experience dilution of your holdings due to the inability to participate in rights offerings.

We may, from time to time, distribute rights to our shareholders, including rights to acquire securities. Under the deposit agreement, the depositary will not distribute rights to holders of ADSs unless the distribution and sale of rights and the securities to which these rights relate are either exempt from registration under the Securities Act with respect to all holders of ADSs, or are registered under the provisions of the Securities Act. The depositary may, but is not required to, attempt to sell these undistributed rights to third parties, and may allow the rights to lapse. We may be unable to establish an exemption from registration under the Securities Act, and we are under no obligation to file a registration statement with respect to these rights or underlying securities or to endeavor to have a registration statement declared effective. Accordingly, holders of ADSs may be unable to participate in our rights offerings and may experience dilution of their holdings as a result.

We expect to incur increased costs as a result of being a public company, particularly after we cease to qualify as an “emerging growth company.”

We are a public company and expect to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and Nasdaq, impose various requirements on the corporate governance practices of public companies. These rules and regulations increased our legal and financial compliance costs and made some corporate activities more time-consuming and costly. As of December 31, 2021, we were no longer an “emerging growth company” pursuant to the JOBS Act. We expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the other rules and regulations of the SEC. For example, we expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, we will incur additional costs associated with our public company reporting requirements. It may also be more difficult for us to find qualified persons to serve on our Board or as executive officers.

We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate with any degree of certainty the amount of additional costs we may incur or the timing of such costs.

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.

Genetron Holdings Limited is an exempted company incorporated under the laws of the Cayman Islands with limited liability. Our corporate affairs are governed by our memorandum and articles of association, the Companies Act (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary duties of our directors to us under Cayman Islands law are governed by the Memorandum and Articles of Association, the Companies Act and 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 compared to U.S. law) as well as from the common law of England. The decisions of the English courts are of highly persuasive authority, but are not binding, on Cayman Islands courts (except for those decisions handed down from Judicial Committee of Privy Council to the extent that these have been appealed from the Cayman Islands courts). The rights of our Shareholders, actions by minority shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are broadly similar to those in other common law jurisdictions, but there may be differences in the statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different body of securities laws as compared to the United States. In addition, if shareholders want to proceed against the company outside of the Cayman Islands, they will need to demonstrate that they may not have standing to initiate a shareholders derivative action in a federal court of the United States.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders of these companies with the exception that the shareholders may request a copy of the Articles of Association. 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.

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 our board of directors or controlling shareholders than they would as public shareholders of a company incorporated in the United States.

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

We are an exempted Cayman Islands company with limited liability and substantially all of our assets are located outside of the United States. Our current operations are conducted in China. In addition, some of our current directors and officers are nationals and residents of countries other than the United States. Substantially all of the assets of these persons are located outside the United States. 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 China may render you unable to enforce a judgment against our assets or the assets of our directors and officers.

We cannot assure you that the ADSs will remain listed on Nasdaq.

Although it is currently intended that the ADSs will remain listed on Nasdaq, there is no guarantee of the continued listing of the ADSs on any of the exchanges. We may decide at some point in the future to delist voluntarily (subject to the applicable regulatory requirements) from one or more of these exchanges, or we may be delisted involuntarily if, among other factors, we do not continue to satisfy the listing requirements of the applicable exchange or comply with applicable law. We will be delisted from the Nasdaq if the PCAOB continues to be unable to inspect our independent registered public accounting firm for three consecutive years. We cannot predict the effect a delisting of the ADSs on Nasdaq would have on the market price of the ADSs.

There can be no assurance of the accuracy or completeness of certain facts, forecasts and other statistics obtained from various independent third-party sources, including the industry report, contained in this annual report.

This annual report contains information and statistics related to the global and China oncology drug markets. Such information and statistics have been derived from a third-party report commissioned by us and publicly available sources. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, we cannot guarantee the quality or reliability of such source materials. The information in the report and such source materials have not been independently verified by us or the Company's respective directors, officers, employees, partners, agents, advisors and any other parties involved in connection with this annual report and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics included in this annual report being inaccurate or not comparable to statistics produced for other issuers or markets. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. You should consider carefully the importance placed on such information or statistics.

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.

As long as we qualify as a foreign private issuer under the Exchange Act, we will be 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 results on a quarterly basis as press releases, distributed pursuant to the rules and regulations of the Nasdaq. 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.

Although we believe we were not a passive foreign investment company (“PFIC”) for 2021, due to our ADSs’ price fluctuations there is a significant risk that we will be a PFIC for 2022 or any future taxable year, which could result in adverse U.S. federal income tax consequences to U.S. investors in the ADSs or our ordinary shares.

In general, a non-U.S. corporation is a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the average value of its assets consists of assets (generally determined on a quarterly basis) that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and certain gains. Cash is a generally passive asset for these purposes. Goodwill is an active asset under the PFIC rules to the extent attributable to activities that produce active income.

Based on the composition of our income and assets and the estimated value of our assets, including goodwill, we believe that we were not a PFIC for our 2021 taxable year. However, our PFIC status for any taxable year is an annual determination that can be made only after the end of that year and will depend on the composition of our income and assets and the value of our assets from time to time. We hold a substantial amount of cash and while that continues to be the case our PFIC status for any taxable year will depend primarily on the average value of our goodwill. The value of our goodwill may be determined, in large part, by reference to our market capitalization. Because our market capitalization has been volatile and declined substantially in recent months, if the value of our goodwill is determined by reference to our market capitalization and the market price of the ADSs does not increase sufficiently, there is a significant risk that we will be a PFIC for our taxable year 2022, and possibly future taxable years. Moreover, it is not entirely clear how the contractual arrangements between us and the VIEs will be treated for purposes of the PFIC rules, and we may be or become a PFIC if the VIEs are not treated as owned by us for these purposes. For these reasons, there can be no assurance that we will not be a PFIC for or any taxable year.

If we are a PFIC for any taxable year during which a U.S. investor owns the ADSs or our ordinary shares, the U.S. investor generally will be subject to adverse U.S. federal income tax consequences, including increased tax liability on disposition gains and “excess distributions” and additional reporting requirements. This will generally continue to be the case even if we cease to be a PFIC in a later taxable year, unless certain elections are made. See “Taxation—Material U.S. Federal Income Tax Consideration—Passive Foreign Investment Company.”

As an exempt 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 Stock Market corporate governance listing standards; these practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq Stock Market corporate governance listing standards.

As an exempted Cayman Islands company listed on the Nasdaq, we are subject to the Nasdaq Stock Market corporate governance listing standards. However, the Nasdaq Stock Market rules 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 Stock Market corporate governance listing standards. We may elect to rely on home country practice to be exempted from the corporate governance requirements. As a result, our shareholders may be afforded less protection than they would otherwise enjoy under the Nasdaq Stock Market corporate governance listing standards applicable to U.S. domestic issuers. See “Item 16.G. Corporate Governance” for detailed discussion of such exemption.

ITEM 4. INFORMATION ON THE COMPANY

4.A. History and Development of the Company

We launched our clinical diagnosis and monitoring services in 2015 with the establishment of Genetron Health (Beijing) Co., Ltd. (“Genetron Health”).

We underwent a series of restructuring transactions, which primarily included:

- In April 2018, Genetron Holdings Limited was incorporated under the laws of the Cayman Islands as our proposed listing entity. In connection with its incorporation, it issued ordinary and preferred shares to certain of the then existing shareholders of Genetron Health based on their equity interests held in Genetron Health.
- In June 2018, Genetron Health (Hong Kong) Company Limited, or Genetron HK, was incorporated in Hong Kong, which is acting as the offshore intermediary holding company.
- In March 2019, Genetron (Tianjin) Co., Ltd., was established in China as a wholly owned PRC subsidiary of Genetron HK. Genetron (Tianjin) Co., Ltd. is not engaged in substantive business operations in the PRC. In July 2019, Genetron (Tianjin) Co., Ltd. entered into a series of contractual arrangements with Genetron Health, as well as its shareholders. As a result of these contractual arrangements, we obtained effective control, and became the primary beneficiary of Genetron Health.
- In December 2020, Genetron HK formed a joint venture with Wuxi municipal government and established Genetron (Wuxi) Business Management Co., Ltd. in China as a subsidiary of Genetron HK. Genetron HK owns 90% equity interest in Genetron (Wuxi) Business Management Co., Ltd. Genetron (Wuxi) Business Management Co., Ltd. is not engaged in substantive business operations in the PRC. In December 2020, Genetron (Wuxi) Business Management Co., Ltd. entered into a series of contractual arrangements with Genetron (Wuxi) Biotech Co., Ltd., as well as its shareholders. As a result of these contractual arrangements, we obtained effective control, and became the primary beneficiary of Genetron (Wuxi) Biotech Co., Ltd.

Genetron is a holding company and does not directly own any substantive business operations in the PRC. We currently focus our business operations within the PRC primarily through Genetron Health and its subsidiaries. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Corporate Structure.” Genetron Health and its subsidiaries hold our Medical Institution Practicing Licenses, production permits of medical devices and operation permits of medical devices that are necessary for our business operations in the PRC.

In June 2020, we completed an initial public offering in which we offered and sold an aggregate of 80,000,000 ordinary shares in the form of ADSs. Upon the initial public offering, all of our then issued and outstanding preferred shares were automatically converted into ordinary shares on a one-for-one basis. On June 19, 2020, the ADSs began trading on the Nasdaq under the symbol “GTH.”

Our corporate headquarters is located at 1-2/F, Building 11, Zone 1, No.8 Life Science Parkway Changping District, Beijing, People’s Republic of China. Our registered office is located at the offices of Walkers Corporate Limited, 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands. Our telephone number is +86 10 5090-7500. Our corporate website is www.genetronhealth.com. The information contained on or that can be accessed through our website is not incorporated by reference into this annual report, and you should not consider information on our website to be part of this annual report.

The SEC maintains an internet site at www.sec.gov that contains reports, information statements, and other information regarding issuers that file electronically with the SEC.

Recent Regulatory Developments

Cybersecurity Measures

On December 28, 2021, the CAC and several other administrations jointly published the Measures for Cybersecurity Review Measures, effective on February 15, 2022. Pursuant to the Measures for Cybersecurity Review, (i) the purchase of network products and services by a “critical information infrastructure operator” (the “CIIO”) and the data processing activities of a “network platform operator” that affect or may affect national security will be subject to the cybersecurity review; (ii) if a “network platform operator” who possesses personal information of more than one million users intends to go public in a foreign country, it must apply for a cybersecurity review with the Cybersecurity Review Office; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if they determine certain network products, services or data processing activities affect or may affect national security. As of the date of this annual report, the number of users whose information possessed by us is far below one million. Additionally, substantial uncertainties exist with respect to the interpretation and implementation of the Measures for Cybersecurity Review. For example, it is unclear whether the requirement of cybersecurity review applies to follow-on offerings by an “online platform operator” that is in possession of personal data of more than one million users where the offshore holding company of such operator is already listed overseas.

Earlier, the CAC also issued on November 14, 2021 a consultation draft of its Cyber Data Security Administration Regulations (the “Draft Administration Regulations”), which, among other things, stipulates that a data processor listed overseas must conduct an annual data security review by itself or by engaging a data security service provider and submit the annual data security review report for a given year to the municipal cybersecurity department before January 31 of the following year. As of the date of this annual report, the Draft Administration Regulations has not been formally adopted. However, if it were enacted in the current form, we, as an overseas listed company, will be required to carry out an annual data security review and comply with the relevant reporting obligations. As of the date of this annual report, we have not been involved in any investigations on cybersecurity review made by the CAC on the national security basis or any other basis, and have not received any inquiry, notice, warning, or sanctions in such respect. However, we cannot guarantee that we will not be subject to any cybersecurity review in any future offering of securities outside the PRC.

For detailed discussion regarding the cybersecurity review related risks, see “Item 3. Key Information—3.D. Risk Factors—Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, investigation or sanction by regulatory authorities, private litigation, other liabilities, and/or adverse publicity. Non-compliance or failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.”

Potential CSRC Approval Required for Maintaining the Listing of our ADSs

On July 6, 2021, certain PRC regulatory authorities issued Opinions on Strictly Cracking Down on Illegal Securities Activities. These opinions call for strengthened regulation over illegal securities activities and supervision on overseas listings by China-based companies and propose to take effective measures, such as promoting the development of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies. As of the date of this annual report, no official guidance and related implementation rules have been issued in relation to these recently issued opinions and the interpretation and implementation of these opinions remain unclear at this stage.

On December 24, 2021, the CSRC published the draft Administrative Provisions of the State Council on the Overseas Issuance and Listing of Securities by Domestic Companies (Draft for Comments) (the “Administrative Provisions”), and the draft Measures for the Overseas Issuance and Listing of Securities Record-filings by Domestic Companies (Draft for Comments) for public comments. These draft regulations stipulate that PRC domestic companies that seek to offer and list securities in overseas markets directly or indirectly shall complete the filing procedures with and report relevant information to the CSRC. Pursuant to these drafts, if the issuer meets the following conditions, its offering and listing will be deemed as an “indirect overseas offering and listing by a PRC domestic company” and is therefore subject to the filing requirement: (i) the revenues, profits, total assets or net assets of the Chinese operating entities in the most recent financial year accounts for more than 50% of the corresponding data in the issuer’s audited consolidated financial statements for the same period; (ii) the majority of senior management in charge of business operation are Chinese citizens or have domicile in PRC, and its principal place of business is located in PRC or main business activities are conducted in PRC. The domestic enterprises should submit filing documents to CSRC within three business days after the submission of the application for overseas initial public offering, and after completing the filing procedures for an overseas initial public offering and listing, for the purposes of implementing and strengthening the CSRC’s supervision, the issuer will need to comply with continuous filing and reporting requirements after such offering and listing, among others, including the following: (i) reporting material events which arose prior to such offering and listing, (ii) filing for follow-on offerings after the initial offering and listing, (iii) filing for transactions in which the issuer issues securities for acquiring assets, and (iv) reporting material events after the initial offering and listing. However, the Draft Overseas Listing Regulations and the Draft Overseas Listing Measures were released for public comment only, there remains substantial uncertainty, including but not limited to its final content, adoption timeline, effective date or relevant implementation rules. As of the date of this annual report, we cannot predict the impact of these regulations on maintain the listing status of our ADSs and/or other securities, or any of our future offerings of securities overseas in a foreign country. Additionally, we cannot assure you that we will not be required to obtain the approval of or complete the filing with the CSRC or other regulatory authorities to maintain the listing status of our ADSs on the Nasdaq or to conduct overseas securities offerings in the future. For details of the associated risks, see “Item 3. Key Information—3.D. Risk Factors—Risks Related to Doing Business in the PRC—We may be required to obtain approval or complete filing or other requirements of the CSRC or other PRC government authorities in connection with our issuances of securities overseas, and, if required, we cannot predict whether we will be able to obtain such approval or complete such governmental procedure.” We have been closely monitoring regulatory developments in China regarding any necessary approvals from the CSRC or other PRC regulatory authorities required for overseas listings and securities offerings. As of the date of this annual report, we have not received any inquiry, notice, warning, sanctions or regulatory objection from the CSRC in this regard.

Implication of the Holding Foreign Companies Accountable Act

The Holding Foreign Companies Accountable Act (the “HFCA Act”), was enacted on December 18, 2020. The HFCA Act states if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for three consecutive years beginning in 2021, the SEC shall prohibit our shares or ADSs from being traded on a national securities exchange or in the over-the-counter trading market in the United States. On December 16, 2021, PCAOB issued the HFCA Act Determination Report, according to which our auditor is subject to the determinations. Our auditor, the independent registered public accounting firm that issues the audit report included elsewhere in this annual report, as an auditor of companies that are traded publicly in the United States and a firm registered with the PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. Since our auditor is located in China, a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the PRC authorities, our auditor is currently not inspected by the PCAOB. Final rules implementing the submission and disclosure requirements in the HFCA Act were adopted by the SEC on December 2, 2021 and became effective on January 10, 2022. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment. The PCAOB is currently unable to inspect our auditors in relation to their audit work performed for our financial statements and inability of the PCAOB to conduct inspections over our auditors deprives our investors with the benefits of such inspections. For the details of the risks associated with the enactment of the HFCA Act, see “Item 3. Key Information—3.D. Risk Factors—Trading in our ADSs on the Nasdaq Stock Market or in the over-the-counter market will be prohibited, and as a result, our ADSs will be delisted under the HFCA Act, if the PCAOB is unable to inspect or fully investigate auditors located in China. On December 16, 2021, the PCAOB issued the HFCA Act Determination Report, according to which our auditor is subject to the determinations that the PCAOB is unable to inspect or investigate completely. The delisting of our ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment. If this happens there is no certainty that we will be able to list our ordinary shares on a non-U.S. exchange or that a market for our ordinary shares will develop outside of the United States.”

4.B. Business Overview










We are a leading and fast-growing precision oncology platform company in China that focuses on full-cycle cancer management by utilizing advanced technologies in molecular biology and data science. We have developed a comprehensive NGS-focused product and service portfolio that covers the entire spectrum of cancer care from early screening, diagnosis and therapy selection, to continuous monitoring and care.

COMPREHENSIVE DIAGNOSIS SERVICE AND PRODUCT PORFOLIO

The increasing diversity of targeted therapies and associated molecular biomarkers has given rise to comprehensive genomic profiling, particularly in tumor types where multiple genomic targets can be found and treated effectively. We offer comprehensive genomic testing across all common cancer types using both comprehensive and focused assays. Our comprehensive diagnosis service and product portfolio is designed to test and analyze patients of various cancer types for clinically-relevant genomic mutations to support treatment selection. We believe that our suite of multi-tiered services and products with proven reliability, sensitivity and specificity for clinical practice are able to provide physicians with actionable insights into each patient's cancers. With in-depth knowledge of advantages and limitations of both tissue and liquid biopsies, we have developed our services and products to be flexible in sample requirements. Depending on the nature of the cancers, most of our diagnosis services could be performed by testing either tumor samples or different kinds of liquid samples, such as blood, saliva, urine, or cerebrospinal fluid ("CSF").

The following table presents our comprehensive service and product portfolio for LDT service:

LDT service menu

Cancer Types	Diagnosis	Monitoring
 Pan-cancer	● ●	●
 CNS	● ●	●
 Lung	● ●	●
 Gastric	● ●	●
 Colorectal	● ●	●
 Thyroid	●	
 Breast	●	
 Bladder	●	●
 Hematologic	●	●

● Tissue biopsy ● Liquid biopsy

Tissue Based Comprehensive Genomic Profiling — Onco PanScan™

Our comprehensive genomic profiling service, Onco PanScan™, is applicable for all solid tumor patients, including newly diagnosed patients, patients with drug resistance and patients with disease relapse. Clinical utility of the Onco PanScan™ is rapidly expanding, as an increasing number of driver mutations are identified and an increasing number of novel cancer drugs are approved by the FDA or NMPA.

Onco PanScan™ features the following strengths:

- it detects single nucleotide variants ("SNVs"), insertions and deletions ("InDels"), fusion, copy number variants ("CNVs") and the key immunotherapy biomarkers: tumor mutation burden and microsatellite instability;

- it is composed of 825 genes including approximately 125 genes as CDx biomarkers intended to guide treatment of various cancers as recommended by WHO, National Comprehensive Cancer Network (the “NCCN”), European Society for Medical Oncology (the “ESMO”) and other treatment guidelines, more than 90 genes related to immuno-oncology, more than 150 proto-oncogenes and tumor-suppressor genes, approximately 145 genetic susceptibility genes and 12 cancer signaling pathways;
- it has been comprehensively validated across the entire panel, especially on those clinically actionable mutations;
- it provides comprehensive genomic profiles in an easy-to-read report for physicians and patients;
- it is compatible with both Illumina and MGI sequencing platforms; and
- it could be commercialized as an IVD product, if approved by NMPA or similar regulatory agencies, in addition to LDT service currently provided; indeed, Onco PanScan™ obtained the CE Mark in November 2021.

The comprehensive and evolving coverage of genes, high level of precision and lower sample volume requirements make Onco PanScan™ suitable for targeted therapy guidance, immunotherapy guidance, cancer genetic risk assessment, evaluation of chemotherapy efficacy, molecular classification and disease monitoring across a wide variety of cancer types, as well as key information for new scientific discoveries. Data from the Onco PanScan™ was presented at the AACR meeting in 2022, which identified the fusion landscape and germline variation in both glioma and sarcoma. Besides, the differences of genetic mutation between paediatric and adult sarcoma were demonstrated. These results proved that Onco PanScan™ is capable of assisting diagnosis and treatment of gliomas and sarcomas in clinic. We plan to leverage on the success of Onco PanScan™ as an LDT service and intend to seek the NMPA's approval of Onco PanScan™ as an IVD assay, which will be compatible for Genetron S2000. We have completed analytical validation/typing test for Onco PanScan™ IVD assay administered by the National Institutes for Food and Drug Control, a prerequisite to start a clinical trial to validate the test. We expect to commence patient enrollment in 2022.

Liquid Biopsy-Based Comprehensive Genomic Profiling — Onco Tracker™

To accommodate different needs, we have developed a liquid biopsy-based comprehensive genomic profiling, Onco Tracker™. Such versatility has tremendous clinical benefits. Because Onco Tracker™ is designed as a pan-cancer testing panel to cover a wide range of cancer indications, it is critical for such pan-cancer testing panel to be able to work with different types of testing samples/biopsies, depending on the nature of the cancer types and/or patients' health conditions. Given the practical challenges in obtaining high-quality tumor samples via biopsy, such as acquiring sufficient cancer cells for diagnosis and genomic analysis, we have developed Onco Tracker™, which utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral blood.

Onco Tracker™ is an NGS-based liquid biopsy assay for pan-cancer solid tumors that identifies key genomic alterations and guideline supported biomarkers. Onco Tracker™ contains 170 genes as well as MSI determination. Onco Tracker™ includes 106 genes with strong clinical significance as derived from variants with FDA-approved target therapies, guideline-recommended treatment and international studies. In particular, it covers all the gene variants from the National Lung Matrix Trial (NLMT), a large national NSCLC umbrella study in the United States and all the HRR genes in GALAHAD clinical trial. Onco Tracker™ also includes 64 genes with high frequency of genetic alterations in cancer patients as observed in our proprietary database.

Onco Tracker™ covers over 330 recommended targeted drugs and immunotherapies, of which approximately 100 are approved by the FDA and recommended by the NCCN. It is a qualitative NGS-based assay that uses targeted high throughput hybridization-based capture technology for detection of SNVs, InDels, CNVs, fusion and microsatellite instability (MSI). Onco Tracker™ enables accurate variant detection with more than 30,000X sequencing depth. Onco Tracker™ utilizes UMI-based error correction and precisely measures locus specific noise level. Onco Tracker™ enables informed treatment decisions for advanced solid-tumor cancer patients and identifies treatment options or clinical trials for patients before first-line therapy or at progression. Onco Tracker™ is expected to be launched as an LDT in 2022.

Focused Gene Panel Testing

In addition to comprehensive genomic testing across all cancer types and mid-size gene panel using liquid biopsy, we also offer focused gene panel testing. Focused gene panel testing is a useful tool for analyzing specific mutations in a given sample. Focused gene testing contains a selected set of genes or gene regions that has known or suspected associations with the cancer etiology or treatment. Focused gene panel testing services also produce a smaller, more manageable data set compared to broader approaches such as whole exome sequencing (“WES”). As of the date of this annual report, our focused gene panel testing services cover a variety of cancer types, including CNS, lung, colorectal, thyroid, breast and bladder cancers.

8-gene Lung Cancer Assay (Tissue) (“Lung 8”)

Lung 8 is an IVD assay developed based on our One-Step Seq™ technology platform for the detection of biomarkers for the NSCLC, the most common type of lung cancer. It was approved by the NMPA as a Class III medical device on January 22, 2020. NSCLC biomarkers include mutations of the Epidermal Growth Factor Receptor (EGFR), KRAS, BRAF, Human Epidermal Growth Factor Receptor 2 (HER2) and PIK3CA genes in the DNA, combination of the ALK and ROS1 translocation mutations and MET exon 14 skipping (METex14) mutation in the RNA (collectively, “Covered Gene Mutations”). Several targeted therapy drugs have been approved and recognized by the NCCN as an effective clinical treatment of NSCLC. Through the identification of the presence or absence of any such NSCLC biomarkers, Lung 8 allows physicians to select targeted therapy drug and monitor its potential efficacy.

Lung 8, which is built with our One-step Seq™ Method, substantially reduces operational complexity for library construction. We believe that our Lung 8 has the following advantages:

- *Comprehensive genomic profiling pool.* Lung 8 is able to detect in a single assay seven genes that the 2018 NCCN guidelines recommend for testing in lung cancer patients.
- *Significant clinical value from CDx.* Lung 8 has been approved by the NMPA as an IVD CDx device to identify EGFR 19 del and L858R-positive, metastatic NSCLC patients who are candidates for gefitinib and icotinib tablets, T790M-positive NSCLC patients who are candidates for osimertinib tablets, and ALK fusion gene-positive NSCLC patients who are candidates for crizotinib tablets. We expect to continue to engage in further R&D to develop Lung 8 for its application as an IVD CDx device for other therapeutic product candidates or approved therapeutic product(s) that target other Covered Gene Mutations and seek NMPA approvals to modify the existing Class III medical device registration certificate of Lung 8. We have signed a CDx co-development agreement with Hutchmed to cover Savolitinib for patients with MET exon 14 skipping.
- *Simplified sequencing process, less contamination risk and quick turnaround time.* The library preparation process only involves a single PCR amplification and its corresponding purification, which simplifies the sequencing process as well as prevents possibilities of contamination. This significantly reduces cost and time involved for the sequencing. Specifically, library building only takes 1.5 hours with only 10 minutes of hands-on time. Patients could receive test results in two days. Lung 8 is compatible with both DA8600 (Ion Proton) and Genetron S5 sequencing platforms. We have also developed a proprietary software for Lung 8 to be used together with these platforms. The software analyzes data generated from the assay and generates test reports with simple clicks.

Glioma 13 Biomarker Panel

Glioma is the most common type of primary brain tumor. It has high recurrence and mortality rates. Accurate molecular classification plays a guiding role in subsequent treatments and prognosis. In 2016, the World Health Organization Classification of Tumors of the Central Nervous System, of which Dr. YAN Hai is a co-author, for the first time, introduced the classification of CNS tumors integrated with both histological phenotypes and genotyping, setting up new guidelines for molecular classification in clinical diagnosis and treatment. In particular, IDH1 and IDH2 mutations were included as the most critical biomarkers for adult malignant glioma. Of note, Dr. Yan is one of the pioneers who discovered IDH1 and IDH2 mutations. As it is practiced today, clinical treatment of glioma involves surgery in combination with radiotherapy and chemotherapy. Because the sensitivity to temozolomide (a chemotherapy drug for gliomas) is correlated with the methylation level of the MGMT gene, an accurate measurement of the methylation level of the MGMT gene will better guide the chemotherapy with temozolomide.

The superiority of Glioma 13 biomarker panel is that all the thirteen biomarkers for glioma can be processed with the same sequencing platform and analysis pipeline. While traditionally, different methods were used in detecting different types of alterations. For example, chromosomes 1p and 19q co-deletions are normally detected with fluorescence in situ hybridization (FISH), and MGMT methylation is detected by pyrosequencing methods. These traditional methods are more cumbersome and expensive when combining them into a single test.

Developed based on our proprietary One-Step Seq™ platform, our Glioma 13 biomarker panel testing services provide cost effective solutions to patients, which test 13 genomic alterations commonly recommended by the NCCN, WHO and ESMO treatment guidelines, including TERT, IDH1, IDH2, chr1p/chr19q, chr7, chr10, BRAF, MGMT, H3F3A, HIST1H3B, HIST1H3C and EGFR VIII. We have optimized our One-Step Seq™ Method to detect other types of alterations such as chromosome loss/gain, gene fusion (RNA level) or methylation changes, so that we can detect chromosome 1p/19q co-deletions, gain of chromosome 7 and loss of chromosome 10, KIAA1549-BRAF fusion and MGMT methylation in addition to point mutations with this platform. Applicable to patients with glioma, our Glioma 13 biomarker testing assay is suitable for molecular classification, targeted therapy selection, evaluation of chemotherapy efficacy and disease monitoring, as well as key information for scientific discoveries and research.

FusionScan Plus

Drugs targeting gene fusions have been increasingly studied for treatment of cancer patients. In fact, some of the most effective drugs that have been approved for clinical use are targeted at fusion genes such as ALK, ROS1, RET and NTRK1/2/3, among others. To detect gene fusions and drug resistant mutations reliably and accurately is critical to help better select patients for treatment and predict therapy effectiveness. High-throughput sequencing of integrated DNA and RNA is an ideal method to screen gene mutations and fusions. However, current assays based on parallel detection of DNA and RNA can only detect specific gene mutations and fusions, and oftentimes need many different samples. Therefore, there is a strong clinical need for an assay that can simultaneously detect a wide range of gene mutations and fusions, and with lower threshold requirements.

Based on our One-Step™ Seq Method, we have developed an NGS-based assay, FusionScan Plus, which uses integrated DNA and RNA as templates for genetic alteration detection. Among them, DNA can be used to detect mutations in 23 tumor-related genes including those serving as CDx biomarkers to select patients for treatment with novel targeted drugs on the market or in development as well as those that may be associated with resistance to specific targeted therapies, whereas RNA can detect 37 fusion genes including those without a priori knowledge of 5' fusion partner. The analytical performance of FusionScan Plus was assessed using an in-house developed bioinformatic pipeline for data processing and analysis. The fusion detection results of 64 positive clinical formalin-fixed paraffin-embedded ("FFPE") samples showed a sensitivity of 96.88% (95% CI: 89.30%-99.14%) by identifying 62/64 gene fusions; only two clinical samples with poor RNA quality were missed. No false-positive fusion was detected in twelve negative samples, giving a sample-based specificity of 100% (95% CI: 75.75%-100.00%). At the mutation level, 100% (95% CI: 43.85%-100%) sensitivity and 100% (95% CI: 95% CI: 91.80%-100%) specificity were observed in 46 clinical samples. The gene fusions were reliably detectable down to two copies per nanogram of total RNA input in all four commercial standards. The analysis of mutations exhibited a lower limit of detection of 1.0% frequency with 40 ng input DNA. Reproducibility results showed little variation between inter- and intra- run. FusionScan Plus shows high accuracy in the simultaneously detection of gene mutations and fusions without a priori knowledge of 5' fusion partner. It can be used to detect drug sites for cancer patients, even with limited biopsy samples, and presents promising perspectives towards clinical applications. The results were presented at the Association for Molecular Pathology 2021 annual meeting.

EARLY SCREENING

We believe that there is a significant market demand for early screening services and products that allow the development of precision oncology to cover early stage cancers, which would allow physicians to precisely detect and select appropriate interventions at the appropriate stages in the disease's evolution, thus increasing survival rate and decreasing cancer treatment costs.

Milestones of Our Proprietary Early Screening Products and Services Development

Liver Cancer

Our NGS-based Assay - HCCscreen™

HCCscreen™ is an NGS-based, liquid biopsy assay developed to identify HCCs from the surface antigen of the HBV (HBsAg) positive asymptomatic individuals. Our multi-omics HCCscreen™ assay detects ctDNA mutations and methylations, as well as protein biomarkers. The combination of these markers enabled outstanding performance of the assay in a cohort of asymptomatic HBV carriers in a large clinical study. Among a total of 1,615 HBsAg+ individuals, the primary outcome showed that HCCscreen™ achieved 88% sensitivity and 93% specificity, compared with 71% sensitivity and 95% specificity, respectively, by ultrasound plus alpha-fetoprotein (“AFP”) combined. HCCscreen™ also achieved 40.9% positive predictive value (“PPV”) and 99.3% negative predictive value (“NPV”). The study results are summarized in the following tables:

Table 1. HIT Results: Genetron HCCscreen™ Final Analysis (N=1,615)

HCCscreen™ Test	HCC	Non-HCC	Total
Test - Positive	76	110	186
Test - Negative	10	1,419	1,429
Total	86	1,529	1,615
Sensitivity (95% CI)	88% (80%, 94%)		
Specificity (95% CI)	93% (91%, 94%)		

Table 2. HIT Results: Ultrasound + AFP Final Analysis (N=1,615)

Ultrasound + AFP	HCC	Non-HCC	Total
Test - Positive	61	83	144
Test - Negative	25	1,446	1,471
Total	86	1,529	1,615
Sensitivity (95% CI)	71% (60%, 80%)		
Specificity (95% CI)	95% (93%, 96%)		

Furthermore, stratified by tumor size, 49% (28/57) of the cases identified by HCCscreen™ were in early stage, i.e., <3cm. These patients are expected to have much better prognosis than patients with advanced cancer. Additionally, HCCscreen™ achieved sensitivities of 85% for tumor sizes of <3cm, 96% for 3-5cm, and 88% for >5cm. The results are summarized in the following table:

Table 3. HIT Results: Genetron HCCscreen™ Sensitivities by Tumor Size

HCCscreen™ Test	Tumor Size (N=64)			Total
	<3cm	3-5cm	>5cm	
Test Positive	28	22	7	57
Test Negative	5	1	1	7
Total	33	23	8	64
Sensitivity	85 %	96 %	88 %	

To leverage PCR existing presence in China and additional government-led infrastructure, we recently have added a qPCR-based assay, named HCCscan™, to our early screening registrational strategy. In China, PCR has a more established presence and readily available workflows in many hospitals and clinics. After the COVID-19 outbreak, the State Council has required hospitals at the county level and above to establish capability for nucleic acid testing, which further accelerated the PCR in-hospital testing market. We believe that adding HCCscan™ would be a prudent approach. Together with HCCscreen™, the combination of both NGS-based and PCR-based early liver cancer screening assays will provide expanded accessibility of liver cancer early screening to the general public in China and potentially allow us to accelerate early screening market penetration. We initiated patient enrollment for our HCCscan™ registrational study in November 2021.

We believe that our liver cancer early screening assays have the following advantages:

- *Potential first-in-class liver cancer IVD screening assay.* At present, we believe there is no readily available liver cancer IVD screening assay. We believe that HCCscreen™ has the potential to become the first-in-class liver cancer IVD screening assay. We plan to start patient enrollment for HCCscreen™ registrational study in 2022.
- *Outstanding screening performance.* HIT Study data suggested superior performance to that of studies using ultrasound and AFP detection technology and indicated diagnostic value of HCCscreen™ in identifying early-stage HCC.
- *Non-invasive.* Utilizing our ctDNA technology, our liquid biopsy technology can provide important diagnostic indicators for asymptomatic HBV carriers with a non-invasive blood test.
- *New development in government insurance coverage.* In late 2021, DNA methylation and other genetic tests were included in some of Beijing and other provincial insurance programs. We believe that adding a high performing PCR-based assay could potentially expand the coverage of our products.
- *Affordable.* We aim to price our HCCscan™ early liver cancer screening assay competitively so that it would be accessible and affordable to the general public. HCCscan™ can also provide self-pay patients in lower-tier markets with a cost optimal solution.

Colorectal Cancer

Based on our Mutation Capsule™ technology, we have developed a blood-based colorectal cancer early screening assay profiling multi-omics biomarkers including mutation, methylation, and copy number variations from cell-free DNA (cfDNA). The algorithm was trained in a retrospective cohort of 100 colon cancer cases and 100 healthy controls, and validated in an independent cohort of the same size. The assay showed >91% sensitivity with the specificity of 95%. We plan to release full details from this cohort through publication some time in 2022.

Multi-Cancer

Based on Mutation Capsule™ technology, we are developing a multi-cancer assay suitable for esophageal cancer, gastric cancer, colon cancer, liver cancer and lung cancer. The algorithm model of such multi-cancer assay is mainly based on the information of fragmentation and genome-wide methylation status from low depth whole genome sequencing on the Mutation Capsule™ library. The assay showed 68-95% sensitivity at the specificity of 90%. The positive cases were further profiled with a panel of mutation and methylation markers to further improve the specificity and to determine the tissue origin of the cancer. As Mutation Capsule™ technology supports multiplex tests on one sample, this multi-cancer assay does not require a second blood draw for the mutation/methylation profiling test.

Our Development Efforts on Early Screening

We have joined the “AIDS, Hepatitis and Other Major Infectious Disease Control and Prevention” project, one of the 2020 Major National Science and Technology Projects led by the MOST. Specifically, we are responsible for identification and development of biomarkers for early liver cancer detection and the validation of liver cancer early screening assay products. Any products developed through this project will earn green channel fast-track review status with NMPA.

In August 2020, we started participating in the launch of a major national research project for early screening of lung and digestive system cancers led by the MOST. The project is designed to include a multi-center, prospective cohort study in lung cancer of 120,000 high-risk individuals in 20 provinces, as well as a cohort study in digestive system cancer of more than 100,000 patients in urban areas, in China. We believe that as of the date of this annual report, we were the only company in China involved in national key research and development projects for all three of liver, lung and digestive cancer early screening.

In September 2020, we received breakthrough device designation from the FDA for HCCscreen™ “for the qualitative detection of hepatocellular carcinoma (HCC)-associated DNA mutations and methylated DNA in cell-free DNA (cfDNA), and protein biomarkers derived from peripheral blood specimens” and “intended for early detection of HCC in individuals who are designated to be at high-risk for hepatocellular carcinoma due to chronic HBV infection and/or liver cirrhosis.” This designation represents a significant milestone for our plan to expand the geographical reach of HCCscreen™. Our goal is to continue to make clinical progress to potentially bring HCCscreen™ to more patients globally. This FDA designation represents the first, yet an important step, in our effort to achieve that goal.

In November 2021, our early precision lung cancer diagnosis and treatment project, a joint initiative with the West China Hospital of Sichuan University, won the second prize of China's National Science and Technology Progress Award. We stood out as the only award recipient that focused on precision oncology in 2021. The National Science and Technological Progress Award is one of the five National Science and Technology Awards, established by the State Council in China. The award is primarily granted to local citizens and organizations who have made distinguished contributions in technology R&D and innovation, the application of advanced scientific and technology achievements, and the promotion of high-tech industrialization. Led by Professor LI Weimin from West China Hospital of Sichuan University, the initiative received significant support from us. The project revealed the unique molecular genetic characteristics of non-smoking younger lung cancer patients, and established a new low-dose CT screening technique for high-risk populations over the age of 40 in China. The project focused on tackling the issue of missed diagnosis in early-stage lung cancer and built a forecasting model based on imaging. In addition, the research team analyzed lung cancer evolution through multi-omics methods, identified molecular markers for early diagnosis, and solved bottleneck problems associated with molecular subtypes and the use of targeted therapy for early stage lung cancer.

MONITORING AND RECURRENCE DETECTION - MRD PLATFORM

Minimal residual disease (“MRD”) testing is one of the most rapidly evolving and dynamic markets. MRD refers to the small number of cancer cells that can remain in a patient's body after treatment and may eventually cause recurrence of the disease.

Seq-MRD® - Our First Test for Hematologic Cancer and MRD Detection in the China Market

MRD monitoring is becoming increasingly important in the hematologic cancer field because highly effective new therapies are extending survival. NCCN guidelines recommend using a validated test to measure MRD to define the burden of disease and assess response to therapy in MM and ALL after each treatment stage. NGS-based MRD testing has been added to these guidelines.

This has created a need for more sensitive tools to monitor the disease status of patients over longer periods of time and has introduced the potential for MRD to be included as a surrogate or primary endpoint in registrational clinical trials. We believe we are uniquely positioned to benefit from these industry dynamics with both our clinical and biopharmaceutical customers.

In late 2020, we entered an exclusive licensing agreement with Hangzhou ImmuQuad Biotechnologies Co., Ltd. (“ImmuQuad”) to develop and commercialize Seq-MRD®, a diagnostic assay for the detection and monitoring of MRD in select hematologic cancers.

Under the agreement, we have exclusive rights to research, develop, commercialize, and manufacture MRD detection products or testing methods in select hematologic cancers using ImmuQuad’s Seq-MRD® globally. ImmuQuad is eligible to receive high single-digit royalties on product sales for ten years following commercialization. Separately, we made a minority equity investment in ImmuQuad.

Seq-MRD® has been optimized with our One-Step Seq™ technology, which allows the library construction process to complete in a single PCR reaction and minimizes the risk of contamination and false positive results. This simple operational feature, together with our fully automated bioinformatics solutions, enables Seq-MRD® to achieve high throughput, accuracy, cost-efficiency and fast turnaround time.

Seq-MRD® is our first test for the detection and NGS-based monitoring of MRD in patients with B-ALL, MM, and CLL in China. In these hematologic cancers, the malignant cell is derived from a B cell. Because our technology can accurately and reliably identify and quantify DNA of clonal malignant cells at a level equivalent to one malignant cell among one million normal cells, we can monitor MRD accurately at a high sensitivity, given sufficient sample input. By taking a baseline measurement prior to starting therapy and then tracking the clonal DNA at several time points following therapy initiation, hematologists can improve their ability to detect relapse early, help predict patient outcomes and monitor response to therapy.

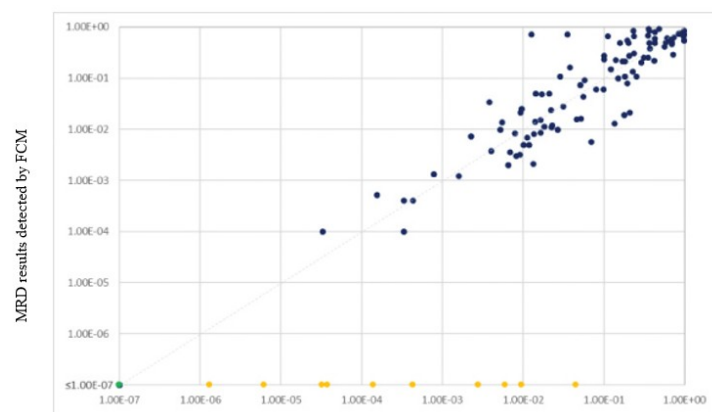
In October 2021, we took one-step further of our commercialization efforts of our Seq-MRD® product by partnering with Jiangsu Fosun Pharmaceutical Sales Co., Ltd. which marks the launch of our first product for hematologic cancer and MRD detection in the China market and makes us one of the first companies to launch MRD products in China.

Seq-MRD Validation Results

MRD results from Seq-MRD® and Flow cytometry (FCM)

A comparison of MRD results detected by Seq-MRD® and FCM in 128 bone marrow specimens (47 B-ALL, 39 CLL, and 42 MM) is presented in the below charts. The positive detection results of FCM and Seq-MRD® were highly consistent. Among them, 10 cases were detected MRD positive by Seq-MRD® but negative by FCM, which suggested the higher sensitivity of Seq-MRD® in this study.

Comparison of MRD results detected by Seq-MRD® and FCM



MRD results detected by Seq-MRD®

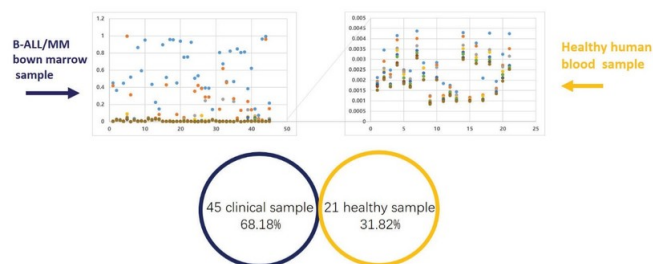
	FCM MRD+	FCM MRD-	PPA (95%CI)	NPA 95%CI)
Seq-MRD+	98	10	100%	66.67%
Seq-MRD-	0	20	(96.23%-100%)	(48.78%-80.77%)

Linearity and Limit of Detection (LOD) analysis in cell lines

The results of gradient experiments of seven cell lines suggested that after the samples were diluted, the MRD values under different level showed an excellent linear relationship with the theoretical value, indicating that Seq-MRD® could be used to track each various levels of MRD accurately, compliant with the expected requirements. When loading 20µg sample, for B-ALL and MM sample, the LOD (Limit of Detection) is 6.5×10^{-7} ; for CLL sample, the LOD (Limit of Detection) is 9.75×10^{-7} .

Limit of Blank (LOB)

The significant clones detected in 45 clinical samples were compared to check whether they were detected in the 21 healthy human blood gDNA samples and verify the abundance of significant clones detected by Seq-MRD® in healthy human samples and the specificity of significant clones traceable.



Solid Tumors MRD — Our Effort to Fill Void in MRD Tests for Solid Tumors in the China Market

In addition to our development and commercialization efforts on MRD tests for hematologic cancers, we are exploring the application of our MRD platform for solid tumors. MRD testing in solid tumors may help in the clinical management for patients, well before metastatic lesions grow to significant size detectable by conventional methods such as MRI and CT scan.

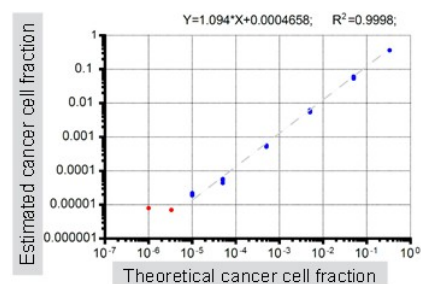
In November 2021, we entered into a collaboration agreement with AstraZeneca R&D China (“AstraZeneca”) for the joint development in China of NGS-based tumor-informed (personalized) MRD tests for various solid tumor types. Using our Mutation Capsule™ technology, this assay will be developed based on the genetic analysis of the primary tumor from individual patients before the treatment. The companies will jointly invest capital for this collaboration, and will work closely to develop and validate the assay for cancer monitoring and recurrence prediction. For solid tumor clinical trials in China that incorporate the use of NGS-based personalized MRD tests, AstraZeneca plans to use the co-developed MRD test in China-specific studies, subject to fulfillment of individual study criteria. The partners may further expand the collaboration to include IVD registration and commercialization of this assay. This is an exclusive, multi-year collaboration agreement between both parties, with exclusivity contingent on certain requirements.

Beyond tumor-informed MRD assay, we are also exploring tumor-naïve MRD approach based on Mutation Capsule™ to evaluate the performance of different types of biomarkers, including mutation, fragmentation, methylation, etc.

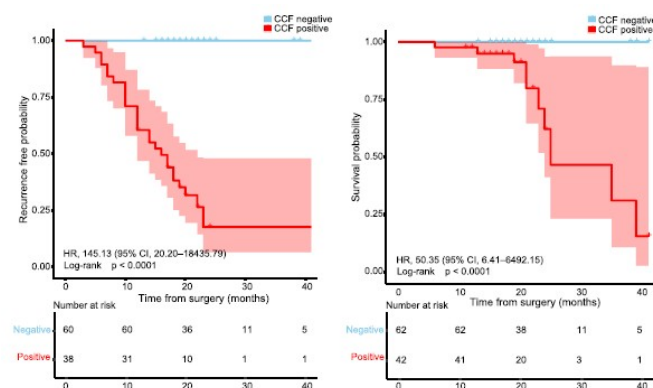
Solid Tumor MRD Analytical Validation Study

We have shown encouraging analytical validation results, as demonstrated by data published in the *Journal of Hematology & Oncology*. A model was developed to detect residual cancer cells among normal cells in peritoneal lavage fluid (PLF), and exhibited high sensitivities with strong linear correlation between theoretical and estimated cancer cell dilution ratios up to 0.001%.

Validated ctDNA fraction model



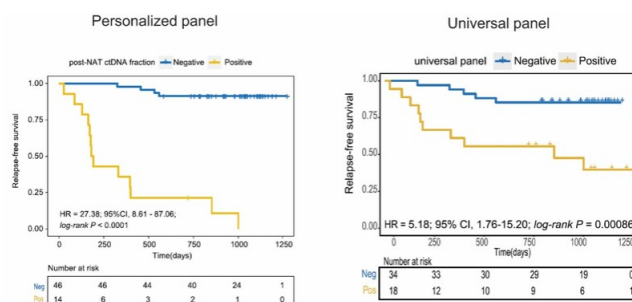
The following figure presents data from a cohort of 104 gastric cancer patients. The assay detected all the cases that developed peritoneal dissemination with 100% sensitivity and 85% specificity from PLF samples. MRD-positive patients were associated with decreased recurrence free survival (RFS) and overall survival (OS).



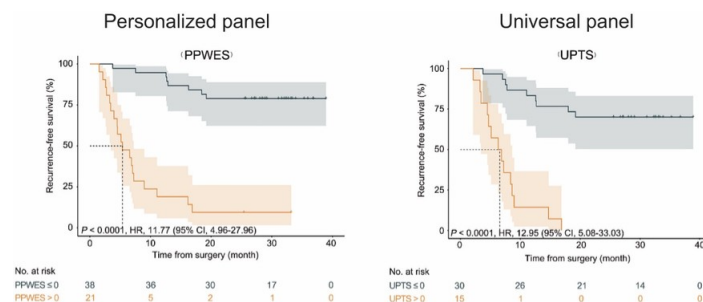
Solid Tumor MRD Prospective Clinical Cohort Study

The Mutation Capsule™ technology has also been applied to clinical validation work comparing MRD profiling between personalized assay and fixed panel in locally advanced rectal cancer and HCC. Early results varied based on different tumor types and clinical application scenarios, and more studies are ongoing to gain additional insights between the two MRD strategies.

The following figure presents the Kaplan-Meier survival results from head-to-head comparisons between personalized and non-personalized assays in locally advanced rectal cancer patients after neoadjuvant therapies. These data were recently published in eBioMedicine, part of *THE LANCET Discovery Science*.



The following figure presents results from head-to-head comparisons between personalized and non-personalized assays in HCC patients. These data have been accepted to be published in a *Clinical and Translational Medicine*.



DEVELOPMENT SERVICES

Our leading position in precision oncology has attracted industry-leading biopharmaceutical companies to establish collaborations with us. We partner with biopharmaceutical companies in China and globally to serve their needs in genomics research and clinical development.

As of December 31, 2021, we had collaborated with approximately 60 biopharmaceutical companies. We are able to provide support to pharmaceutical companies across many applications, including discovery of new targets and mechanisms of acquired resistance, retrospective sample analysis to rapidly identify biomarkers associated with response and lack of response, prospective screening and patient referral to accelerate clinical trial enrollment, and companion diagnostic development to support the approval and commercialization of therapeutics. By doing so, we have stayed at the forefront of the development of targeted drugs, providing us with insights in the latest developments in the industry, which will assist us in exploring future commercialization opportunities.

Our strong technology infrastructure is particularly suitable for collaboration with biopharmaceutical companies. For instance, we developed FusionScan, a customized technology based on a biopharmaceutical company's request for comprehensive and efficient detection of actionable translocation mutations. With a reverse transcription and two PCR reactions, the FusionScan technology can efficiently detect translocations with high sensitivity and low cost. It can detect *de novo* translocation mutations without having to know the other segment fused to the target gene like NTRK or FGFR. Our experienced IVD registration capacity and robust commercial capabilities are appealing to biopharmaceutical companies as well. We believe our collaboration with biopharmaceutical companies will also build evidence of clinical utility for our platform as an effective diagnostic tool for advanced cancer therapies. Our biopharmaceutical company partners include global pharmaceutical companies as well as innovative biopharmaceutical companies in China, such as AstraZeneca China, Bayer, Roche China, Janssen Pharmaceuticals, Innovant Biologics, CStone, InnoCare, Alphamab Oncology, Fosun Pharma, Henlius and EdiGene.

CDx Development and Registration Solutions

We provide end-to-end CDx development and registration solutions for our biopharmaceutical company partners from initial biomarker discovery to commercialization. Supported by our China-U.S. dual R&D centers and experienced regulatory teams, we are one of the few companies with the ability to effectively facilitate the co-development and registration of oncology drugs and their corresponding CDx devices in China and the United States.

Customized CDx Solutions

We provide customized CDx development and registration solutions for our biopharmaceutical company partners to support the approval and commercialization of therapeutics. Our collaboration with CStone for the joint development of a CDx test for avapritinib is an example of such solution offering. The CDx test kit detects the D842V mutation in the human platelet-derived growth factor receptor alpha (PDGFRA) gene using a PCR-based method.

CDx Solutions Built on the Expansion of Application of the Approved IVD Assay

We also offer CDx solutions built on the expansion of application of the approved IVD assay. For example, we are collaborating with HUTCHMED to further develop Lung 8 as IVD CDx devices for Orpathys (savolitinib) in China to treat patients with NSCLC harboring METex14 mutation, and seeks NMPA approval. Lung 8 is one of the few approved NGS-based IVD assays focusing on lung cancers that include METex14 mutation. Once we have completed necessary clinical trials, we plan to submit application to the NMPA to amend the Class III medical device registration certificate for Lung 8 to expand the application scope as IVD CDx devices thereafter.

In addition, in November 2021, we entered into a strategic partnership with NeoGenomics to drive global oncology drug research and development enable business partners to synchronize global clinical drug trials and companion diagnostics development.

DUAL-PRONGED FLYWHEELS ACCELERATING OUR COMMERCIAL AND REGULATORY DEVELOPMENT

We offer NGS-focused product and service through both LDT services and IVD products, the two flywheels supporting our commercial and regulatory development. LDTs examine samples collected from the human body, such as body fluids (blood, urine, cerebrospinal fluid, etc.) and tissue, and are conducted in laboratories.

As a leader for cancer diagnosis and therapy selection services, we have strategically developed our LDT services to provide WES, comprehensive gene panel sequencing and focused gene panel sequencing to address different needs and adapt to complex and evolving understanding of cancer. Our comprehensive diagnostic products and services cover the top ten major cancer types in China, including CNS, lung, liver, colon, breast, urinary system and thyroid and other types of cancers. We sold over 69,000 diagnostic tests in the past three years, with 22,900 in 2019, 21,900 in 2020 and 24,360 in 2021. We have a team of top-notch scientists who are at the forefront of cancer genomics research and are active in the research and discovery of new biomarkers associated with various cancers. Despite the rapid development of LDTs in China in recent years, due to the relatively short history of the LDT industry in China, a comprehensive regulatory framework governing the LDT industry has not been established. There are certain risks associated with the regulatory uncertainties of the provision of our LDT services in China. For details of such risks and regulatory uncertainties, see “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Business and Industry—We may be adversely affected by the uncertainties and changes in the regulation of cancer genomic testing service industry or LDT industry in general in the PRC, and any lack of requisite approvals, permits, registrations or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects.” For details of compliance status of our provision of our genomic LDTs services in China, see “—Regulations—PRC Regulations—Government Consultation Relating to Genomic LDTs.”

In addition, we believe we were the No.1 NGS-based cancer diagnosis and monitoring company in China in terms of the number of NMPA approved IVD assays and platforms as of December 31, 2021. With our NMPA registered IVD products and a deep and robust IVD registration pipeline, we aim to provide hospitals and research institutions in China with one-stop diagnostic and monitoring solutions, which we believe is the key to commercialization success in China. In comparison to our LDT services, our IVD products offer a more standardized, targeted and cost-effective way of detecting genomic mutations relating to cancer.

High Quality LDT Service Offerings

We perform our LDT services primarily in our laboratory located in Beijing. As of the date of this annual report, we held CLIA certificates to perform high-complexity testing for our laboratories in Beijing and Maryland. Our clinical laboratory in Beijing has additionally obtained a certification from the College of American Pathologists (“CAP”) and ISO 15189 certificate issued by American Association For Laboratory Accreditation, being one of the few NGS laboratories in China that have all three international accreditations. Notably, the Beijing clinical laboratory received full marks under the NCCL’s first nationwide EQA of NGS-based comprehensive genomic profiling for solid tumors in August 2021, earning the designation “Outstanding Laboratory” and ranking first among all of the 63 laboratories that participated in the evaluation. In addition, each of our clinical laboratories has obtained NCCL EQA Certifications in various aspects, including our high-throughput sequencing and our bioinformatics platforms. In particular, our clinical laboratories have passed over 240 national and provincial clinical laboratory EQA tests since our inception, covering germline, comprehensive panel and liquid biopsy testing and bioinformatics, demonstrating our dedication to the highest service quality. Previously approved for pilot run, our Guangzhou lab is officially approved by the Guangdong Bureau of the NCCL in December 2021 to offer Onco PanScan™, which makes our Guangzhou lab one of the few laboratory in China approved for conducting NGS-based genomic profiling services. For details of our testing facilities and quality control, see “—Our Manufacturing and Testing Capacity—Our Testing Facilities” and “—Quality Control.”

Enjoying the benefits of our industry leading and differentiated technologies, including Genetron One-Step Seq™ Method, Mutation Capsule™ technology and bioinformatics, we are able to shorten total time for library construction and reduce the time required to analyze DNA samples, with an average turnaround time of six days from the collection of testing samples.

Our LDT services start with a patient’s selection of relevant clinical services tests. Once the selection is made, we will collect a sample (either tumor tissue or body fluids) from the patient. We will then perform genomic sequencing of DNA extracted from the sample. Once the genomic sequencing is completed, we will conduct data analysis and prepare a final test report.

The test report, structurally designed in collaboration with leading oncologists and KOLs, delivers actionable information in a manner designed to seamlessly integrate into their practices. It is divided into multiple sections, presenting crucial genomic information relating to the cancer patient in a concise and practice-friendly manner that facilitates physicians to make treatment decisions. The test results and their clinical significance are summarized at the beginning of the report to give a concise overview. In addition to the most reliable clinical guidelines published by the WHO and NCCN, we also provide physicians with comprehensive information of the detected biomarkers at sub-guideline levels. Our database includes the information of new drugs and biomarkers at clinical trial stage (including enrollment information) and at pre-clinical stage. The report provides a note to each piece of information to clarify its reliability (i.e., whether the information is from any guideline that the physicians are recommended to follow, or such information is from a pre-clinical experiment for reference only). The comprehensive information in the reports helps the physician provide precise treatment to those who have a therapeutic target and approved drug available, and provides off-label and other treatment choices for those who have not.

Evolving IVD Product Portfolio Designed for In-hospital Operations

Supported by the combination of NMPA-approved IVD instruments and assays, we are the leading precision oncology company in China offering de-centralized in-hospital testing solutions. Indeed, we believe we were No. 1 among NGS-based cancer diagnosis and monitoring companies in China in terms of the number of NMPA-approved IVD products, including both instruments and diagnostic assays, as of December 31, 2021. Certain larger-scale hospitals in China prefer to conduct laboratory tests in-house, especially with respect to those relatively standard tests with greater patients' demands. However, despite the large and growing demand for NGS-based cancer molecular profiling services, hospitals face multiple challenges in adopting these services, which have technically sophisticated workflows and strict clinical laboratory environment.

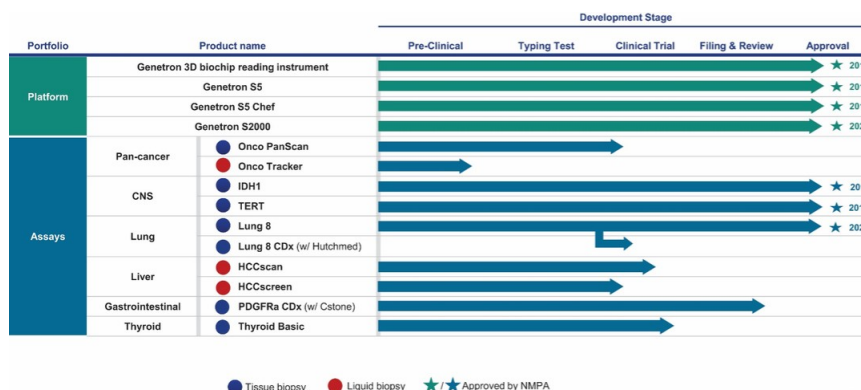
NMPA approvals of IVD products are also the prerequisite to the adoption by these in-hospital centers and insurance coverage. Following its NMPA approval, our Lung 8 was approved for the Sunshine Medical Centralized Procurement in Shandong, Sichuan, Hunan, Jiangxi, Hubei, Guangdong, Zhejiang, Anhui and Qinghai Provinces, Tibet Autonomous Region and Chongqing, Guangzhou, Shenzhen and Dalian Cities, with Gansu, Jilin, Fujian, Hainan and Guangxi Provinces pending for approval, which we regard as a significant step towards obtaining public medical insurance coverage.

Gene sequencing IVD products generally focus on specific sets of genomic alterations relating to a certain cancer type, and are more standardized than LDT services. As such, IVD products are more suitable for hospitals to operate independently. As hospitals rapidly develop their pathology departments and establish their own IVD genomic testing capabilities with increasing number of testing items, demand for IVD products has continued to grow. This is in particular true among top tier hospitals in China.

Leveraging our strong research and development capabilities, we are constantly developing innovative IVD products that enable faster, more accessible and affordable detection of cancer specific genetic alterations. We are one of the few precision oncology players in China with approved IVD registration for both instruments and assays.

The IDH1/TERT gene assays approved by NMPA for glioma diagnosis and Lung 8 for the qualitative detection of NSCLC biomarkers are not only important results of the clinical transformation of our research, but also embodiments of our in-depth promotion of the "LDT services and IVD products" model.

We believe with an in-depth registration pipeline of both instruments and assays, we are able to provide one-stop diagnostic and monitoring solutions for hospitals and research institutions. We have developed a very strong pipeline of IVD products. As of the date of this annual report, we had developed seven NMPA approved IVD products, including four clinical molecular testing instruments and three diagnostics assays. We expect to conduct further regulated clinical trials for our pipeline IVD assay products. Our IVD product portfolio and respective registration status are illustrated as follows:



Comprehensive Solutions Tailored to In-hospital Operations

We have developed the following instruments and assays designed for in-hospital operations. The flowchart below illustrates how our Genetron S5/S2000 and compatible IVD assays such as Lung 8 work together as a simple solutions for in-hospital operations:



Both Genetron S5 and Genetron S2000 are simple to use with cartridge-based reagents and offer superior scalability and flexibility to support a broad range of medium to high throughput sequencing applications, including the NMPA-approved IVD assays such as Lung 8. To properly function as an IVD device for hospitals and other customers, Genetron S5 and Genetron S2000 must work together with a compatible NMPA-approved IVD assay—just like a printer must work together with a compatible ink cartridge. Genetron S5 or Genetron S2000 alone without the NMPA approved compatible IVD assays is not able to serve its intended purpose of generating a clinical report. Therefore, we are developing other IVD assays compatible with Genetron S5 and Genetron S2000 to enrich further applications of our IVD instruments and assay devices.

Genetron S5/Chef System and Lung 8

Genetron S5, approved by the NMPA as a Class III medical device on November 1, 2019, is a semiconductor-based NGS system locally manufactured under an original equipment manufacturer (“OEM”) model, which detects the nucleotide through detecting the change in pH. Compared with other sequencing systems, Genetron S5 does not require fluorescence or camera scanning, resulting in higher speed, better simplicity, lower cost and smaller instrument size. Genetron S5 leverages the speed of semiconductor sequencing to enable the production of high quality sequencing data in a few hours and enables a laboratory technician to go from DNA library to data in as little as 24 hours with only 45 minutes of total hands-on time when paired with the Genetron Chef System. Our NMPA approved Genetron Chef System is a workflow simplification product that incorporates all steps of library preparation and all steps of template preparation and chip loading.

In addition, we developed a simple One-Step library preparation method that offers a fast and efficient procedure for the preparation of high-quality libraries in as little as 1.5 hours from as little as 20ng input samples. Genetron S5 provides a faster and easier way to promote NGS-based genomic testing. Genetron S5 is approved by the NMPA to work as an IVD device that tests FFPE tissue samples. We plan to seek approval from the NMPA to expand application of Genetron S5 to test blood samples, in addition to the FFPE tissue samples.

In order for Genetron S5 to fully function as an NMPA-approved IVD device, it has to work with other NMPA approved IVD assays. Lung 8 is our first NMPA-approved IVD assay compatible with NGS-based instrument. It is developed based on our One-Step Seq™ technology platform for the qualitative detection of biomarkers of NSCLC, the most common type of lung cancer. We also developed a proprietary software for Lung 8 as a plug-in to be used together with its Genetron S5, which analyzes data from the assay and generates test reports with simple clicks. Such software is installed as a plug-in application on Genetron S5, rather than operated on a separate device, which optimizes operational efficiency for in-hospital partners to save laboratory space and reduce extra workflow procedures for conducting NGS genomic testings.

The combination of Genetron S5/Chef System and other One-Step Seq™ technology-enabled compatible assays is designed to provide a flexible and saleable solution for in-hospital operations and enables a broad range of targeted NGS applications with speed and efficiency.

Genetron S2000 and Onco PanScan™

Genetron S2000, approved by the NMPA as Class III medical device on January 22, 2020, is a comprehensive and flexible production-scale sequencer locally manufactured under OEM model. Genetron S2000 adopts an innovative “flow cell” system that can support various sequencing modes, and an optimized optical and biochemical system which enables the whole sequencing process to be completed within a short period of time, offering the user a simplified and streamlined sequencing experience. Genetron S2000 supports different sequencing application such as whole genome sequencing and focused gene sequencing. Genetron S2000 enables comprehensive genomic testing for high-throughput clinical testing centers such as large hospitals and regional medical testing centers.

To maximize Genetron S2000’s clinical value as a high-throughput IVD instrument for in-hospital operations, we intend to seek the NMPA’s approval of Onco PanScan™ as an IVD assay, which will be compatible for Genetron S2000. We expect to commence patient enrollment in 2022. Genetron S2000 is capable of analyzing 32 Onco PanScan™ IVD assays at the same time, which provides significant operational efficiencies to larger hospitals for their in-hospital operations. Together with Onco PanScan™ IVD assay, we believe Genetron S2000 will provide larger hospitals and regional medical testing centers with a valuable solution to comprehensive genomic testing.

Assays developed on qPCR platform

In China, PCR has a more established presence and readily available workflows in many hospitals and clinics. After the COVID-19 outbreak, the State Council has required hospitals at the county level and above to establish capability for nucleic acid testing, which further accelerated the PCR in-hospital testing market. To leverage PCR existing presence in China and additional government-led infrastructure, we believe our current approved IDH1 and TERT gene assays and other pipeline IVD assays on PCR platform, such as Thyroid Basic, PDGFRA test for GIST cancer, and HCCscan™ will provide smaller and mid-sized hospitals with more options:

- **IDH1 and TERT Gene Assays.** Approved by the NMPA and having received a CE Mark, our IDH1 and TERT assays detect IDH1 R132H, TERT C228T and C250T gene mutations in brain tumors and could be a crucial tool for purposes of molecular classification and prognosis of a patient's glioma. IDH1/TERT gene assays are capable of detecting low-frequency (1%) gene mutations in 10ng of DNA sample. In a clinical trial of IDH1 assay with 1,192 valid samples, in which Sanger sequencing was used as the reference method, our IDH1 gene assay demonstrated 100% sensitivity and 100% specificity, with Kappa value at 1.000 ($p < 0.001$). We believe our IDH1/TERT gene assays are the first specific IVD products approved by NMPA to support in-hospital testing of brain cancer.
- **Thyroid Basic Assay.** Thyroid Basic assay detects BRAF V600E, TERT C228T and C250T gene mutations in thyroid tumors, which are considered an essential tool for molecular classification and prognosis of a patient's thyroid tumor. Thyroid Basic is capable of detecting low-frequency (1%) gene mutations in 20ng of DNA sample. Thyroid Basic has completed analytical validations/typing test required to initiate clinical trials in China. A clinical trial at four clinical sites are currently undergoing to establish its clinical effectiveness based on pathological examination and/or clinical diagnosis and to assure its analytical accuracy as compared to Sanger sequencing.
- **PDGFRA Assay.** The human PDGFRA gene D842V mutation detection kit (PCR- fluorescent probe method) under development is intended for qualitative detection of PDGFRA gene exon 18 D842V mutation in FFPE tissue samples from patients with GIST. It is developed as the companion diagnostic test for treatment of GIST patients with Avapritinib tablets in a co-development collaboration with our pharma partner. The test demonstrates significant agreement with the sanger sequencing method in a total of 1,041 samples. The positive percent agreement (PPA) is 100%, the negative percent agreement (NPA) is 99.23%, and the Kappa value is 0.92 ($P < 0.001$). A registration application has been submitted to the NMPA and has received priority review status.
- **HCCscan™.** Guidelines for The Diagnosis and Treatment of Primary Liver Cancer (2019 Edition) recommends abdominal ultrasound and serum alpha- fetoprotein (AFP) for surveillance or screening of HCC, but the performance of the recommended methods vary widely due to the skills of the operators and conditions of patients. As a result, there is an urgent need for new biomarkers for more efficient diagnosis of HCC. We developed HCCscan™, a qPCR-based assay that can help identify patients with HCC based on a proprietary panel of six DNA methylation markers that high levels in liver cancer patients as compared to non-liver cancer population.

Based on qualitative detection of methylation of markers in cell free DNA (cfDNA) samples, HCCscan™ is intended for clinical early screening of primary liver cancers, especially in population with high-risk profile of liver cancer, such as HBV and/or HCV infection, excessive drinking, nonalcoholic steatohepatitis, long-term consumption of food contaminated by aflatoxin, liver cirrhosis caused by various other reasons, and family history of liver cancer.

HCCscan™ offers the following advantages over the current standard of care procedures:

- it offers convenience as a non-invasive test that only requires a simple blood draw;
- it reduces operator-to-operator variability independent of patient's physical conditions;
- it has equivalent or better performance in terms of specificity and sensitivity based on early research; and
- it employs qPCR, a widely available testing platform in tertiary hospitals and community care centers.

A registrational clinical trial to enroll over 4,500 HBV-positive patients is ongoing at several leading research centers across China and is expected to be completed in 2022 for us to seek registration approval for HCCscan™ by the NMPA as a Class III medical device in 2023.

Dedicated Efforts Supporting In-hospital Operations

With our expertise in NGS-based cancer molecular profiling, knowledge in regulatory environment and NMPA-approved IVD portfolio, we have assembled a dedicated team to work side-by-side with in-hospital partners throughout the process of developing their own in-hospital molecular diagnostics centers, from laboratory redesign, equipment procurement and system installation to ongoing training, support and on-demand consultation. With these molecular diagnostics centers and laboratories, equipment and reporting systems in place, we sell them our instruments, IVD assays and reagent kits on a recurring basis, which allow them to perform testing on their own in a standardized manner. Our well-trained sales team meets with hospitals' representatives and doctors regularly, providing latest updates on the clinical utility of precision oncology in China, introducing our services and products and providing solutions to their technical questions.

Our solutions for in-hospital operations are well accepted by many in-hospital partners. As of December 31, 2021, we have partnered with 58 hospitals, 30 of which are IVD in-hospital partners. Revenue generated from sales of IVD products increased by 64.4% to RMB154.5 million (US\$24.3 million) in 2021 from RMB94.0 million in 2020, which was mainly driven by sales of Genetron S5 and Lung 8. As we continue to advance our Onco PanScan™ IVD assay registration with NMPA, we believe our Genetron S2000 and Onco PanScan™ IVD assay combo will bring our in-hospital partners more benefits, in particular, operational efficiencies.

OUR PROPRIETARY TECHNOLOGIES

We believe our technologies, supported by our owned and licensed patents, together with our trade secrets and industrial know-hows, have set us apart from our competitors and made us a leader in cancer genomics, and more broadly, precision oncology medicine. Our core technologies, especially our proprietary Mutation Capsule™ and Genetron One-Step Seq™ Method, which is enhanced by liquid biopsy low-frequency mutation detection technology, have enabled us to continuously deliver high-quality results while minimizing cost, operational complexity and operational turnaround time.

Mutation Capsule™ Technology

We have developed Mutation Capsule™, a method for detecting mutation and methylation of tumor specific genes in ctDNA, and it supports both our early screening tests, as well as our tumor-informed and tumor naive assay developments. In March 2022, the China National Intellectual Property Administration granted an invention patent to Mutation Capsule™.

Compared to technologies that only detect a subset of alterations, Mutation Capsule™ technology can detect a broad spectrum of ctDNA alterations, including simple mutations, such as SNVs and InDels, complicated mutations, such as translocations, HBV integrations and CNVs and methylation changes. The parallel profiling of genomic and epigenetic alterations in a single reaction enables comprehensive profiling of ctDNA biomarkers with minimal sample requirement. In addition, Mutation Capsule™ technology supports multiple tests of one ctDNA sample without having to split samples and sacrificing sensitivity. To achieve this, we add DNA barcode and amplify ctDNA to generate a "mutation capsule™ library" ("MC Library"), which supports up to ten tests on different panels of biomarkers. After a test, the remaining MC Library could be used to detect new biomarkers in future test plans. The sensitivity of each test on the MC Library is generally equivalent to the initial test directly on the original ctDNA sample, which could directly reflect mutation of the original DNA. In this case, a ctDNA sample collected in one study could be used to test new biomarkers in multiple different studies. One major hurdle of performing liquid biopsy study is not only to acquire blood samples, but also to track the individual to know the clinical outcome. With Mutation Capsule™ technology, clinical outcome of one study could benefit multiple studies. Moreover, certain new studies could be completed even without collecting and tracking new samples or cohorts. We believe our proprietary Mutation Capsule™ technology significantly saves our time and costs associated with future clinical trials and research studies and will increase the efficiency of our R&D efforts.

Furthermore, the MC Library supports both amplification and hybridization-based capture to enrich target region, which allows us to study a wide range of panel sizes. Even at panel size as small as 10Kb, this technology keeps high (>80%) on-target rate, significantly increasing the efficiency of sequencing and lowering the cost. The DNA barcode added to the ctDNA molecule, in combination with our bioinformatic program, will filter false positive mutations from amplification and sequencing.

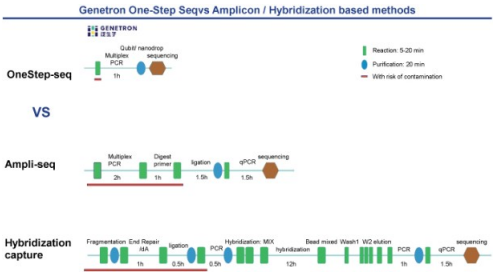
The following table reflects comparisons of different sequencing technologies:

	Mutation Capsule™	Hybridization based ctDNA sequencing	Amplification based ctDNA sequencing
Mutation types to detect	SNV, indel, complicated mutations (CNV, HBV integration, translocation, etc.)	SNV, indel, complicated mutations	SNV, indel
Methylation change	detect in parallel with mutations	in separate reaction to mutations	in separate reaction to mutations
Range of panel size	Small to large	Large	Small
On-target rate for small panel	High	Low	High
High GC region (TERT promoter region for example)	Comparable to normal GC regions and can amplify in parallel	Much lower coverage	Much lower coverage, need to amplify
Reagent cost	Low for amplification-based	High	Low
Sequencing throughput	Flexible	High	Low
Support multiple tests and available for future study	Yes, support multiple amplification- and/or hybridization-based tests	Yes, support multiple hybridization-based tests	No, one sample only supports one test

The combination of these characteristics makes Mutation Capsule™ well suited for cancer early detection and MRD studies—low cost yet high sensitivity. In addition, multiple types of ctDNA alterations can be detected in one reaction, and one sample can be used in multiple studies with different panels of biomarkers tested.

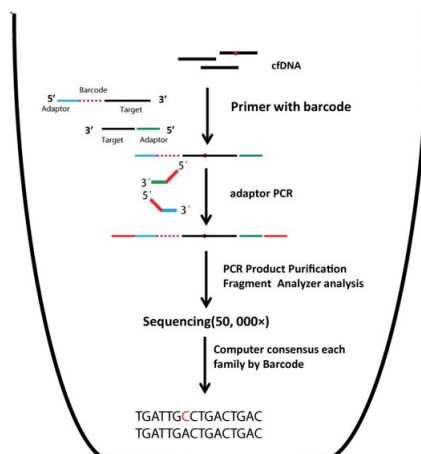
Genetron One-Step Seq™ Method

Applicable to small to medium gene panels, our One-Step Seq™ library construction is based on one-step multiplex PCR technology, which simplifies traditional technologies to a fast and convenient process. The traditional library construction technology involves a multiple- step process: construction of genomic library followed by hybridization-based enrichment of the target region, or multiplex PCR to amplify the target region and then adding adaptors to the PCR product. These strategies need complicated experiments with more than ten steps. Contamination could happen in the steps before the DNA is amplified. The One-Step Seq™ Method allows a DNA library to be prepared directly through a one-step multiplex PCR reaction, minimizing the labor and the risk of contamination. The One-Step Seq™ Method uses the Qubit method for library quantitation instead of qPCR, which requires much less cost and time than the qPCR quantitation required for the library constructed by amplicon based sequencing and other traditional methods. A brief comparison of Genetron One-Step Seq™ Method against hybridization based capture and amplicon based sequencing is shown below:



Genetron One-Step Seq™ Method achieves automatic chemical reaction. The primers and adaptors are mixed with DNA sample in one tube for the multiplex PCR reaction. The primers are specially modified with a special molecule linked to the DNA. Taking into consideration the balance among primer pairs, we have built a program to design up to 10,000 pairs of primers in parallel, which is key to its superior performance. We have optimized the program through numerous rounds of experiments and are able to design the primers with a higher success rate. In addition, the reaction buffer, enzyme, and the PCR program have all been optimized with our extensive know-how.

A brief explanation of our One-Step Seq™ Method is shown below:



We believe that our One-Step Seq™ Method has the following advantages compared to traditional DNA sequencing process when applied to small to medium gene panels and can therefore contribute significant value at the clinical application stage:

- **Less time for library construction:** Through the reduction of the required number of intermediate steps, One-Step Seq™ Method substantially reduces the time of library construction to as little as 1.5 hours compared to 24 hours using hybridization based capture and eight hours using amplicon based sequencing method.
- **Higher quality of the library:** Our One-Step Seq™ Method minimizes the difference among primer pairs, leading to higher quality (balanced coverage among amplicons) of the library and higher success rate of primer design.
- **Lower risk of cross-contamination:** The entire library construction process is completed in sealed centrifuge tubes with minimal hands-on time, which significantly reduced the risk of cross-contamination.
- **Lower production costs:** We produce assays developed based on this method with simple raw materials such as water, primer and enzyme, instead of purchasing commercial assays from third parties. Our lower production costs provide us with flexibility in pricing strategies. We believe this flexibility will enable us to achieve greater hospital acceptance and potential national drug reimbursement list inclusion in the future, as compared to our competitors, which are factors especially important for commercializing IVD products.

- *Greater operational simplicity:* Our One-Step Seq™ Method has less demand on operational space, making it particularly suitable for space-constrained hospitals to conduct genomic testings.
- *Lower sample amount DNA input:* Our One-Step Seq™ Method starts from a sample amount as low as 1ng DNA and has lower sample requirements in order to achieve successful library construction.

The following comparison chart illustrates the advantages and limitations using different methods:

	Genetron One-Step Seq™	Amplicon Based Sequencing	Hybridization Capture
DNA input requirement	Low (as low as 1 ng)	Low	High
Hands-on steps and time	Very simple (10 min)	Complicated (40 min)	Very complicated
Total time (from DNA to library)	1.5h	8h	24h
Contamination risk	Low	High	High
Laboratory section requirement	Low	Medium	High

Our One-Step Seq™ platform is further enhanced by our liquid biopsy low-frequency mutation detection technology. Biomarkers like EGFR mutation are critical for the diagnosis and treatment selection of cancer patients. In the absence of tumor tissue samples, detection of the mutations from the ctDNA in the blood, urine and CSF of the cancer patient is still possible. However, the mutation frequency could be much lower in these sources of samples. As such, a more sensitive technology is required for the detection of mutations in ctDNA. We are well experienced in ctDNA detection technology, and have developed multiple products to detect low frequency mutations.

We have integrated the DNA-barcode based technology into the One-Step Seq™ platform. By adding a special DNA barcode between the amplified DNA molecule and the adaptor, the false positive errors from PCR amplification and next generation sequencing would be efficiently filtered so that we can detect low-frequency mutations with high fidelity. Meanwhile, the Genetron One-Step Seq™ process minimizes loss of original ctDNA molecule during library construction. The limited ctDNA yield of the testing sample is one of the primary impediments of ctDNA based liquid biopsy, and higher transfer rate from ctDNA sample to detectable library means higher sensitivity to detect mutations. In this case, the combination of DNA-barcode technology and One-Step Seq™ process provide high sensitivity and specificity to detect low fraction mutations in ctDNA. The integration of the two technologies is particularly challenging to organize a series of molecular biology reactions, including amplification of target region, addition of barcode, and addition of adaptor, to take place in order, with all the reagents and primers mixed in the same tube.

As of the date of this annual report, we apply liquid biopsy low-frequency mutation detection technology in the following areas, all of which have achieved a high sensitivity and specificity yield and our assays are able to detect 0.05% mutation:

- *Blood samples:* we extract the ctDNA sample from the patient's blood. Relative to a tissue biopsy, collecting a blood sample is minimally invasive. It is particularly suitable for minimal residual disease ("MRD") testing, which is used to examine whether a cancer treatment is working and to guide further treatment plans.
- *CSF samples:* surgical extraction of brain biopsy is risky, whereas detection of ctDNA from blood for the purpose of detecting CNS cancer is infeasible due to the brain-blood barrier.
- *Urine samples:* we extract DNA from patient's urine sediments. Urine samples could be used to diagnose bladder cancer and other urinary system cancer types, which offers patients a painless sample collection experience. The non-invasive nature of urine samples is also suitable for cancer monitoring services.

We have successfully applied Genetron One-Step Seq™ Method into certain of our products, such as Lung 8, as well as Seq-MRD. In March 2020, we entered into a strategic collaboration agreement with MGI, under which MGI will integrate our One-Step Seq™ technology-enabled assays with its DNBSEQ-G400 and DNBSEQ-G50 platforms. Such strategic collaboration will enable both parties to jointly explore the overseas market. As of the date of this annual report, our One-Step Seq™ technology enabled commercial assays on two out of three mainstream sequencing platforms, including Thermo Fisher Scientific and MGI. Leveraging the advantages of Genetron One-Step Seq™ Method, our IVD products are particularly suitable for hospitals to carry out their own tests.

Bioinformatics

Integration of AI and big data analytics approaches such as machine learning, deep learning, and natural language processing to tackle the challenges of scalability and high dimensionality of data and to transform big data into clinically actionable knowledge is expanding and becoming the foundation of precision oncology. Our AI technology is able to automatically analyze DNA sequencing data to generate a ready-to-read data report.

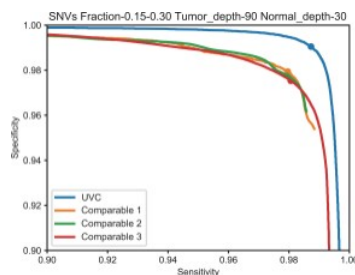
As part of our AI technology capabilities and building on years of experience working with our patients, we have generated high quality genomic data, which contains approximately 270,000 accumulated tissue and blood genomic test results. We believe we also have one of the world's largest brain tumor genomic databases containing data of approximately 29,000 cases, which comprises quality samples that have been compared and cross-referenced with the patient's personal medical history to ensure their clinical significance and accuracy. Our database will continue to grow along with the increasing number of tests we conducted, enabling us to continuously refine our database and enhance its predictive capability.

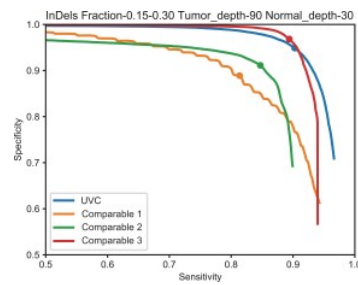
As an important part of our bioinformatics platform, we have developed our own algorithms to optimize the process for variant calling in most of our NGS products. In November 2021, we published a new computational method in *Briefings in Bioinformatics* demonstrating performance improvements of the UVC (Unity-of-opposites Variant Caller) algorithm. The publication describes the outperformance of UVC versus other variant callers on the GIAB germline truth sets, 192 scenarios of in silico mixtures simulating 192 combinations of tumor/normal sequencing depths and tumor/normal purities, the GIAB somatic truth sets derived from physical mixture, and the SEQC2 somatic reference sets derived from the breast-cancer cell-line HCC1395. UVC achieved 100% concordance with the manual review conducted by multiple independent researchers on a 71-gene-panel dataset derived from 16 patients with colon adenoma.

Other key findings from the publication include:

- By utilizing extreme-case analysis to build statistical models, researchers found new principles to improve variant calling.
- Researchers performed comprehensive evaluation on all NGS scenarios that were evaluated involving different samples, assays, sequencing platforms, tumor and normal purities and sequencing depths, human reference genomes, aligners, and calling modes. Their evaluation shows that UVC indeed performs well in all the evaluated NGS scenarios.
- UVC may have important applications in clinical NGS and is especially useful for accurately detecting cancer mutations.

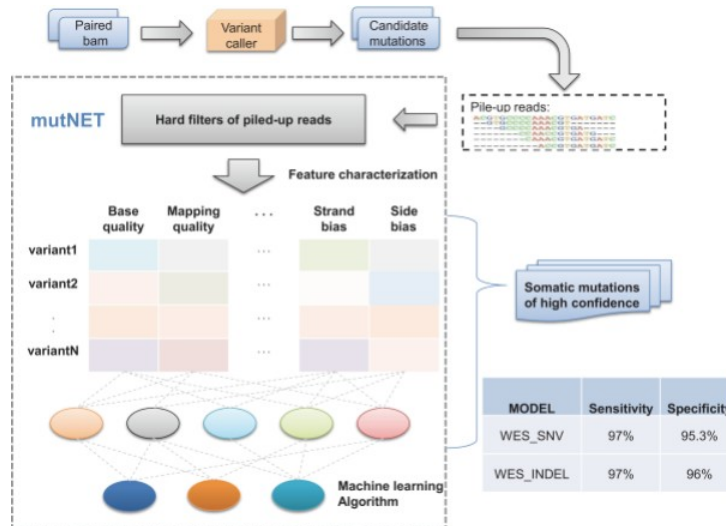
The figures below show the precision-recall curves for calling SNVs and InDels on the GIAB somatic true sets for our variant caller-UVC, in comparison to other commonly used variant callers.





We also developed an automated variant reviewer, mutNET, based on a machine learning framework to replace the manual variant review process. mutNET reduced the variability due to human judgment during the manual review process and cut down 95% of the review time.

The below graph illustrates the workflow and performance of mutNET in our somatic mutation calling pipeline for whole exome sequencing data.



Further, we have applied AI technologies in the development of diagnostic tests for detecting early stage cancers. We applied advanced machine learning technologies to integrate different types of biomarkers for an algorithm, to select key biomarkers for a simple assay for large-scale application, and to optimize our model and product of cancer early detection with enlarged cohort studies. We also trained our bioinformatics pipeline with our evaluation of mutations from clinical outcome to call low-frequency mutations with higher fidelity. These approaches led to increased accuracy of our early screening services. Our diagnostic classifier, a method to detect early stage cancers currently based on our algorithm for liver cancer, was published in *PNAS*.

OUR RESEARCH AND DEVELOPMENT CAPACITIES

We believe our continued research and development is the key driving force behind our long-term competitiveness, as well as our future growth and development. Our overall objective is to continuously broaden the spectrum of our services and products in order to detect a wider range of cancers and to optimize the treatment of cancer.

Our industry leading research team and achievements

Our R&D capacities are supported by our research and development team led by scientists at the forefront of cancer genomics research. Dr. YAN Hai, our Chief Scientific Officer, and Dr. JIAO Yuchen, our Chief Technology Officer, lead our in-house research and development team consisting of 292 researchers and scientists, including 53 Ph.D. degree holders and 140 Master's degree holders across medical, pharmaceutical, molecular biology, biotechnology and other related areas. Dr. YAN Hai obtained his M.D. from Peking University Health Center and his Ph.D. in molecular and cellular biology from Columbia University and received his postdoctoral training in Dr. Bert Vogelstein Laboratory at the Howard Hughes Medical Institute and Johns Hopkins University School of Medicine. Dr. Yan has published over 100 articles in peer reviewed journals, including *New England Journal of Medicine*, *Nature*, and *Science*, as the first or corresponding authors. Dr. JIAO Yuchen obtained his M.D. from Peking Union Medical College and his Ph.D. in biological chemistry at the Johns Hopkins University. Dr. Jiao also had his postdoctoral training at Dr. Bert Vogelstein Laboratory at the Howard Hughes Medical Institute and Johns Hopkins University School of Medicine. His research has been published in multiple renowned academic journals such as *Science* and *Nature Genetics*. In addition, we have established R&D centers in Maryland and Beijing.

Our R&D capabilities are further supported by Dr. HU Yun-Fu, our Chief Medical Officer. Under Dr. Hu' supervision, we have built a dedicated and experienced regulatory team and clinical development team. Dr. Hu brings over two decades of experience in regulatory and managerial capacities related to medical devices and pharmaceutical industries to our team. During his tenure of over ten years at the FDA, he led a team of staff in pre-market reviews and post-market compliance of one of the first kind of IVD products and LDT services for genetic testing, molecular cancer diagnostics, companion diagnostics, radio dosimetry, digital pathology and AI devices.

Our R&D capabilities are well-recognized in the industry. We have obtained an approval from the National Development and Reform Commission of the PRC to establish a national demonstration center for cancer genomic testing technologies. We believe we are one of the top NGS-based cancer diagnosis and monitoring companies in the PRC in terms of the number of articles published in peer-reviewed scientific journals with impact factor over 12.

In September 2020, we received breakthrough device designation from the FDA for HCCscreen™ “for the qualitative detection of hepatocellular carcinoma (HCC)-associated DNA mutations and methylated DNA in cell free DNA (cfDNA), and protein biomarkers derived from peripheral blood specimens” and “intended for early detection of HCC in individuals who are designated to be at high-risk for hepatocellular carcinoma due to chronic HBV infection and/or liver cirrhosis.” We believe this is the first PRC genomic testing company receiving such designation.

The table below summarizes some of our research collaborations and the related journal publications:

Publication Date	Research Institutions/Hospital	Article Title	Journal Title	Journal Impact Factor
June 2014	Beijing Tiantan Hospital Capital Medical University	<i>Exome sequencing identifies somatic gain of function PPM1D mutations in brainstem gliomas</i>	Nature Genetics	38.330
September 2014	Cancer Hospital Chinese Academy of Medical Sciences	<i>Genetic landscape of esophageal squamous cell carcinoma</i>	Nature Genetics	38.330
March 2015	Huashan Hospital	<i>Recurrent gain-of-function USP8 mutations in Cushing's disease</i>	Cell Research	25.617
May 2015	Zhejiang Provincial People's Hospital	<i>Recurrent TERT promoter mutations identified in a largescale study of multiple tumor types are associated with increased TERT expression and telomerase activation</i>	European Journal of Cancer	9.162
April 2016	Beijing Cancer Hospital	<i>Clonality analysis of multifocal papillary thyroid carcinoma by using genetic profiles</i>	Journal of Pathology	7.996
September 2016	Huashan Hospital Affiliated to Fudan University	<i>The genome wide mutational landscape of pituitary adenomas</i>	Cell Research	26.617
May 2017	Huashan Hospital Affiliated to Fudan University	<i>Germline mutations in CDH23, encoding Cadherin-Related 23, are associated with both familial and sporadic pituitary adenomas</i>	American Journal of Human Genetics	11.025
May 2018	Zhejiang Provincial People's Hospital	<i>The genomic landscape of TERT promoter wildtype-IDH wildtype glioblastoma</i>	Nature Communications	14.919
August 2018	Huashan Hospital Affiliated to Fudan University	<i>Identification of recurrent USP48 and BRAF mutations in Cushing's disease</i>	Nature Communications	14.919
October 2018	Cancer Hospital Chinese Academy of Medical Sciences	<i>Sensitive and rapid detection of TERT promoter and IDH mutations in diffuse gliomas</i>	Neuro-Oncology	12.300
November 2018	Beijing Tiantan Hospital Capital Medical University	<i>Molecular profiling of tumors of the brainstem by sequencing of CSF-derived circulating tumor DNA</i>	Acta Neuropathologica	17.088
March 2019	Cancer Hospital Chinese Academy of Medical Sciences	<i>Detection of early-stage hepatocellular carcinoma in asymptomatic HBsAg-seropositive individuals by liquid biopsy</i>	Proceedings of the National Academy of Sciences of the United States of America	11.205
June 2019	China-Japan Union Hospital of Jilin University	<i>MTAP Loss Promotes Stemness in Glioblastoma and Confers Unique Susceptibility to Purine Starvation</i>	Cancer Research	12.701
January 2020	West China Hospital, Sichuan University	<i>Mutation Profile of Tibetan Lung Cancer Revealed by Whole Exome Sequencing</i>	Journal of Thoracic Oncology	15.609
June 2020	Beijing Tiantan Hospital Capital Medical University	<i>The integrated genomic and epigenomic landscape of brainstem glioma</i>	Nature Communications	14.919
August 2020	Peking Union Medical College Hospital	<i>Positive tumour CD47 expression is an independent prognostic factor for recurrence in resected non-small cell lung cancer</i>	ESMO Open	5.329
September 2020	Cancer Hospital Chinese Academy of Medical Sciences	<i>Integrated molecular characterization reveals potential therapeutic strategies for pulmonary sarcomatoid carcinoma</i>	Nature Communications	14.919
October 2021	Cancer Hospital Chinese Academy of Medical Sciences	<i>Personalized analysis of minimal residual cancer cells in peritoneal lavage fluid predicts peritoneal dissemination of gastric cancer</i>	Journal of Hematology and Oncology	17.2
November 2021	Cancer Hospital Chinese Academy of Medical Sciences	<i>Calling small variants using universality with Bayes-factor-adjusted odds ratios</i>	Briefings in Bioinformatics	11.62
March 2022	Cancer Hospital Chinese Academy of Medical Sciences, Peking Union Medical College Hospital	<i>Response prediction and risk stratification of patients with rectal cancer after neoadjuvant therapy through an analysis of circulating tumour DNA</i>	eBioMedicine, part of THE LANCET Discovery Science	8.14

Our research and development capabilities are acknowledged by the PRC government. As a leading precision oncology company, we are accredited as a National High-Tech Enterprise, after being evaluated at all factors, including core independent intellectual property rights and the ability to apply the scientific and technological achievements.

Our research and development capabilities are also supported by our rich intellectual property portfolio. See “—Intellectual Property” for detailed discussion of our patent and patent applications.

R&D Plan

We have developed innovative technology platforms since our inception, including Genetron One-Step Seq™ Method, ctDNA low frequency mutations detection technology and Mutation Capsule™. We are fully committed to investing in R&D to develop new clinical services and IVD products. In the next three to five years, we expect to focus our near-term R&D efforts on early screening, MRD and seek NMPA registration of IVD products covering early screening of liver cancer, lung cancer, digestive cancer and multi-cancer, as well as diagnosis monitoring products such as large-panels, and other blood-based MRD and NGS assays.

R&D Expenses

We have invested RMB91.7 million, RMB149.0 million and RMB254.0 million (US\$39.9 million) in research and development for the years ended December 31, 2019, 2020, and 2021, respectively, accounting for 28.4%, 35.1%, and 47.7% of our revenue for the respective periods, demonstrating our strong commitment in R&D.

INTELLECTUAL PROPERTY

Protection of our intellectual property is fundamental to the long-term success of our business. Specifically, our success is dependent on our ability to obtain and maintain protection for our technology and the know-how related to our business, defend and enforce our intellectual property rights, and operate our business without infringing, misappropriating, or otherwise violating valid and enforceable intellectual property rights of others.

Our patent strategy is focused on seeking coverage for our core technology, such as one-step library construction method, our sequencing platform, our assay, and specific follow-on applications and implementations for detecting, monitoring and early screening cancer or other diseases by determining genetic variations in patient samples. In addition, we file for patent protection on our ongoing research and development which may be applicable in cancer cases and other diseases.

As of December 31, 2021, we owned or co-owned eight issued patents and 26 pending patent applications in China, one issued patent in the United States, one issued patent in South Korea, three pending patent applications in the United States, nine pending patent applications in Europe, Japan, South Korea and Singapore and two Patent Cooperation Treaty (PCT) applications that have not entered national stage. Our patents cover our key technologies, including Mutation Capsule™ (Chinese Patent No. CN201910983038.8), Genetron One-Step Seq™ Method (Chinese Patent No. CN106835292) and liquid biopsy library construction sequencing analysis. We also owned 95 registered trademarks, copyrights to 40 software programs developed by us relating to various aspects of our operations, and nine registered domain names as of December 31, 2021. Our issued patents have expiration dates ranging from May 2030 to June 2041. If patents are issued on our pending patent applications, the resulting patents will be expected to expire between September 2035 to June 2041, subject to any potential patent term extension or adjustment.

The key patents that we own include:

- Method for rapidly constructing amplicon library through one-step process
- Construction method of amplicon library for detecting low-frequency mutation of target gene
- Mutation Capsule™ technology

We obtained an exclusive worldwide license from a leading research institution under certain patent rights make, use and sell products related to TERT mutation analysis.

We seek to ensure that investments made into the development of our technology are protected by relying on a combination of patents, trademarks, copyrights, trade secrets, including know-how, license agreements, confidentiality agreements and procedures, non-disclosure agreements with third parties, employee disclosure and invention assignment agreements and other contractual rights. We have also employed internal policies, confidentiality agreements, encryptions and data security measures to protect our proprietary rights. However, there can be no assurance that our efforts will be successful. Even if our efforts are successful, we may incur significant costs in defending our rights. From time to time, third parties may initiate litigation against us alleging our infringement of their proprietary rights or declaring their non-infringement of our intellectual property rights. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Intellectual Property.”

OUR MANUFACTURING AND TESTING CAPACITY

Our Manufacturing Facilities

We use OEM model to manufacture our sequencing instruments, and all our assays are manufactured in-house. We carry out our manufacturing activities at two facilities located in Beijing and Chongqing. Our Beijing manufacturing facility has a total gross floor area of 402 square meters and is used for the production of our assays. Beijing manufacturing facility had designed annual production capacity of 100,000 assays with utilization rate being approximately 36% and 77% in 2019 and 2020, respectively. Beijing manufacturing facility's designed annual production capacity further increased to 250,000 assays in 2021 and utilization rate was approximately 69% in 2021. Our Chongqing manufacturing facility mainly assembles and manufactures medical devices and has a designed annual production capacity of 500 sequencing platforms. Utilization rate of Chongqing manufacturing facility was approximately 9.78%, 19.11% and 23.2% in 2019, 2020 and 2021, respectively. The manufacturing process of our medical devices takes approximately ten days while the manufacturing of our assays typically takes one month. Both Beijing and Chongqing manufacturing facilities have passed verification of quality management system for medical device registration.

Our Testing Facilities

We have four clinical laboratories located at Beijing, Shanghai, Chongqing and Guangzhou in China, and one in Maryland, USA. Our clinical laboratories are equipped with sequencing platforms to support our cancer molecular profiling services. Our sequencing instruments include such as Illumina Novaseq 6000 and HiSeq XTen, as well as Thermo Fisher S5 Plus and BGI SEQ2000. As we progress with the construction of our new operating center in Wuxi, we intend to include another clinical laboratory as part of the building plan.

All our clinical laboratories in Beijing, Shanghai, Chongqing and Guangzhou have conducted registrations and obtained the Medical Institution Practicing License. Our clinical laboratory in Beijing has obtained comprehensive panel accreditation under the CLIA from the Centers for Medicare & Medicaid Services (“CMS”), a certification from the CAP and ISO 15189 certificate issued by American Association For Laboratory Accreditation, being one of the few NGS laboratories in China that have all three international accreditations. The Beijing clinical laboratory also received full marks under the NCCL's first nationwide EQA of NGS-based comprehensive genomic profiling for solid tumors in August 2021, earning the designation “Outstanding Laboratory” and ranking first among all of the 63 laboratories that participated in the evaluation. In addition, each of our above mentioned clinical laboratories has obtained NCCL EQA Certifications in various aspects, including our high-throughput sequencing and our bioinformatics platforms. In particular, our above mentioned clinical laboratories have passed over 240 national and provincial clinical laboratory EQA tests since our inception, covering germline, comprehensive panel and liquid biopsy testing and bioinformatics, demonstrating our dedication to the highest service quality. Furthermore, our Beijing manufacturing facility has achieved ISO 15189: 2012 certification, ISO 13485: 2016 certification and ISO 9001 2015 certification. Previously approved for pilot run, our Guangzhou lab is officially approved by the Guangdong Bureau of the NCCL in December 2021 to offer Onco PanScan™, which makes our Guangzhou lab one of the few laboratory in China approved for conducting NGS-based comprehensive genomic profiling services. Our Maryland lab in the US is also CLIA-certified.

Quality Control

We believe that an effective quality management system is critical to ensuring the quality of our products and services. We have established a strict in-house quality management system and devoted significant attention to quality control of our raw materials, equipment, products and services. We have established detailed quality control and assurance procedures guiding our internal production and external purchase of raw materials and equipment. We purchase our raw materials and equipment only from selected reputable suppliers. We have implemented quality control system for the designing, R&D, testing and manufacturing of our products. We have adopted a “quality-by-design” approach pursuant to which manufacturing processes are designed during the research and development stage and quality control processes are continuously monitored. Furthermore, our Beijing manufacturing facility has achieved ISO 13485: 2016 certification and ISO 9001 2015 certification. Both Beijing assays manufacturing facility and Chongqing platform manufacturing facility have met the requirements under GMP of medical devices. In addition, each of our medical devices, including platforms such as Genetron 3D biochip reading instrument, Genetron S5, Genetron Chef, and Genetron S2000 and assays such as IDH1 assay, TERT assay, and Lung 8, has also satisfied such requirements. We believe we are one of the earliest precision oncology companies in China that obtained both CAP accreditation and CLIA certification for NGS platform.

Supply of Raw Materials and Components

We have a dedicated team to procure required components to meet specific requirements of our hardware products. The primary raw materials and components used in our laboratories for our LDT services and IVD products include medical device sub-components and reagents such as enzymes, plasmid and buffer solution. We procure our raw materials from suppliers in China, the United States, Japan, Germany, South Africa, the Netherlands and Singapore, which we believe have sufficient capacity to meet our commercial needs. We maintain a list of raw material suppliers and review their qualifications on an annual basis by taking into consideration the results of our on-site evaluation of their production facilities, to the extent applicable, as well as factors such as their product quality, business scale, market share and reputation. To monitor the quality of supplies, we implement a standardized operating system by setting out the procedures and guidelines on the procurement of raw materials, quality control inspection, warehousing, testing and storage. In addition, from time to time, we procure genomics sequencing machines. During the past three years, we had not experienced any material shortages or delays in the supply of raw materials. The experience with our suppliers during past four years has provided us confidence in their ability to produce consistent and quality instrumentation, reagents and materials.

We have taken active measures to control the increases in procurement costs. For example, we enter into long-term framework supply agreements with our major suppliers to secure sufficient raw materials and lock the prices of raw materials for the upcoming financial year. We also purchase manufacturing equipment and tools from multiple suppliers to ensure we maintain stable supply at reasonable prices. Furthermore, we are conducting research on certain key raw materials, and upon completion of our research, we seek to manufacture these raw materials in-house to control cost and quality. During the past three years, we had not experienced any material fluctuations in raw material costs that had a material impact on our results of operations.

License and Supply Agreement

In January 2018, we entered into a license and supply agreement with an international NGS instrument manufacturer (the “International Licensor”), pursuant to which the International Licensor granted a license for us to manufacture a localized version of the International Licensor’s next generation sequencing instruments and diagnostic assays and the International Licensor provides certain sequencers, equipment and other materials that we use in our laboratory operations. During the term of the license and supply agreement, the International Licensor will supply us with sequencing instruments, software, reagents and other consumables for use with the International Licensor instruments.

During the term of the license and supply agreement, we are required to make a rolling quarterly forecast of our expected needs for sequencing instruments, reagents and other consumables for the following four quarters, and place purchase orders for sequencing instruments, reagents and other consumables. Subject to discounts that vary depending on the volume ordered and an annual price adjustment, the price for instruments, reagents and other consumables is based on contract prices that are fixed for a set period of time and may increase in proportion to increases in the International Licensor’s published US list price for equivalent products. The license and supply agreement includes a minimum purchase requirement and requires us to source substantially similar products from the International Licensor.

The agreement contains negotiated use limitations, representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the license and supply agreement is five years and may be renewed by written mutual agreement. Either we or the International Licensor may terminate the license and supply agreement for the other's uncured material breach, bankruptcy or insolvency-related events.

OEM Collaboration Agreement

In December 2018, we entered into an OEM cooperation agreement with a domestic NGS instrument manufacturer (the "Domestic Licensor"), for it to provide certain sequencers, equipment and other materials that we use in our laboratory operations and grant a license allowing us to assemble and manufacture instruments and consumables. During the term of the OEM cooperation agreement, the Domestic Licensor will supply us with sequencing instruments, reagents and other consumables for use with the Domestic Licensor instruments.

During the term of the OEM cooperation agreement, we are required to make a rolling monthly forecast of our expected needs for reagents and other consumables for the following three months, and place purchase orders for instruments, reagents and other consumables. The Domestic Licensor may not unreasonably reject conforming purchase orders. Subject to discounts that vary depending on the volume of instruments and consumables ordered, the price for instruments, reagents and other consumables is based on contract prices that are fixed for a set period of time. The OEM cooperation agreement includes a minimum purchase requirement.

The agreement contains negotiated use limitations, representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the OEM cooperation agreement is six years (or five years starting from the date when we obtain the regulatory approval for the instruments) and may be renewed by written mutual agreement. Either we or the Domestic Licensor may terminate the OEM cooperation agreement for the other's uncured material breach, bankruptcy or insolvency-related events, acquisition by competitors or unpermitted assignment.

SALES AND MARKETING

As of December 31, 2021, we had established a robust sales and marketing team of approximately 390 members to provide doctors, patients and other clients with the customized support. Since 2017 and as of December 31, 2021, we had provided products and services to patients in over 500 hospitals in China. We have also established an external sales network of distributors, covering tier-three and tier-four cities in China. In addition, our dedicated marketing team, responsible for promoting our services and products, ideas and mission of our Company, facilitated our commercialization efforts through leveraging both online platforms and offline channels, and both self and collaborative initiatives, to our existing customers and potential new customers. Our marketing team will also co-sponsor or organize medical summits, conferences and seminars each year to promote and raise awareness of the clinical application of precision oncology among physicians and patients.

Direct Sales

As of December 31, 2021, our direct sales team covered 36 cities, including four tier-one cities, located in 25 provinces in China.

The majority of our business is derived from direct sales to patients, which is divided into three business units, focusing on diagnosis and monitoring services, early screening services and development services, respectively.

We believe that the precision oncology market requires further education and guidance on the benefits of genomic screening of cancer. In this regard, our sales and marketing team is well-positioned to guide and educate the market, driving market penetration in the markets we selected. In anticipation of our business expansion and as more of our pipeline products obtain approval for commercialization, we plan to further expand our sales and marketing force in the next few years.

Sales through Distributors

In addition to our direct sales, we also sell our services and products to our end customers such as hospitals through our distributors. We monitor the sales activities of our independent third-party distributors from time to time, including the levels of inventory of IVD assays and sequencing platforms and the sales volume of LDT diagnostic testing services at our distributors. We believe that our distribution model is consistent with customary industry practice and serves to complement our direct sales. In particular, to provide a wider and more comprehensive sales network, we engage our distributors mainly to penetrate into tier-three or tier-four cities and selected regions in China. Combining both our sales and marketing team and our distributors network, we believe we are able to provide a more comprehensive sales network within China compared to our peers.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

We believe our continued growth rests on integrating social values into our business. We have been dedicated to creating a lasting positive environmental, social, and governance (“ESG”) impact on our customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities.

We have implemented a number of company-wide measures to ensure compliance with the stringent regulatory requirements and standard operating procedures relating to emissions of air, water and other materials, bio-waste generation and treatment, handling, use, storage, treatment and disposal of hazardous substances, worker health and safety requirements, and emergency planning and response. We have dedicated biosafety experts responsible for biosafety training, compliance of our operations with biosafety-related legal requirements, biosafety risk assessment and review of corrective actions and preventative actions that we will take upon the occurrence of any biosafety emergency. We have implemented a climate change management system based on the recommendations of the Task Force on Climate-related Financial Disclosures (“TCFD”) under the Financial Stability Board (“FSB”) to identify risks and opportunities related to climate change, and improve management to reduce greenhouse gas emissions in the Group’s operations and mitigate the impact on climate change, based on the results.

As of the date of this annual report, we are not subject to significant environmental or climate-related risks. However, growing concerns about climate change and greenhouse gas emissions have led to the adoption of various regulations and policies. The estimated magnitude of resulting impacts is evaluated over short-, medium and long-term horizons. In recent years, changing weather patterns due to climate change have increased in frequency of extreme weather conditions. Disasters created by extreme conditions could cause significant interruption to our operations. In the medium to long-term, increasingly enacted legislation and regulations in response to potential impacts of climate change may have the potential to impact our operations directly or indirectly as a result of required compliance by our customers or our supply chain, and may subject us to additional costs and restrictions, which could negatively impact our financial condition and results of operations. Any inconsistency of such laws and regulations may also affect our costs of compliance.

COMPETITION

Growing understanding of the importance and effectiveness of precision oncology medicine is leading to more companies offering services and products in the industry. In the China market, due to various regulations, we are mainly competing with domestic players. Our competitors may include companies providing cancer molecular profiling, third-party service providers specializing in diagnosis and monitoring services, and upstream suppliers. We primarily compete on a number of factors, including efficiency and turnaround time for report preparation, support by KOLs, our product pipelines, technology platforms, ability to commercialize products, strong R&D and IVD registration capabilities.

We expect the competition in the precision oncology market to persist and intensify. Our competitors may announce or develop new clinical services, products or enhancements that allow for a more precise detection and/or quicker turnaround. They may also establish clinical trial sites or conduct preclinical testing and clinical trials with new scientific approaches that better cater for the medical needs of patients. We believe our comprehensive LDT services, deep IVD registration pipeline and R&D capability form a barrier to entry and provide us with competitive advantages. However, we cannot assure that we will continue to compete effectively. For more information, see “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Business and Industry—We may face intense competition and our competitors may develop similar, but more advanced services and products than ours, which may adversely affect our business and financial conditions.”

PROPERTIES AND FACILITIES

We are headquartered in Beijing, China. We have leased offices, manufacturing facilities and clinical laboratories as summarized below. We lease our premises under operating lease agreements from independent third parties, and we plan to renew our leases as needed. We believe that our existing facilities are generally adequate in meeting our current needs, but we expect to seek additional space as needed to accommodate future growth.

Location	Space (in square meters)	Use	Lease Term (months)
Beijing, China	10,187	Office, manufacturing, clinical laboratory, and storage	12 – 60 *
Shanghai, China	1,577	Office and clinical laboratory	12 – 36
Chongqing, China	4,488	Office, manufacturing, clinical laboratory, and storage	63 **
Guangzhou, China	3,421	Office and clinical laboratory	60
Tianjin, China	2,617	Office	17
Tianjin, China	492	Office and outpatient department	60
Wuxi, China	10,800	Office and clinical laboratory	8 – 60 ***
Gaithersburg, MD, USA	544	Office and research and development laboratory	84

* Our facilities in Beijing mainly locate in Changping and Liangmaqiao. Our Changping facilities occupy multiple floors in different buildings at Beijing Life Science Park, and therefore, we entered into multiple lease agreements, the terms of which vary from 12 months to 60 months and will expire from April 2022 to January 2026. We are in the process of renewing the lease agreement for a clinical laboratory that expired in April 2022, and we do not expect any difficulties in such renewal. Our Liangmaqiao facilities mainly serve as office and has term of 42 months, which will expire in March 2024.

** The current lease agreement for our facilities in Chongqing expired on December 31, 2021. We are in the process of renewing the lease agreement, and we do not expect any difficulties in such renewal.

*** The construction of new operating center in Wuxi is work-in-progress. The term of the lease agreement started on January 1, 2022.

INSURANCE

We provide social security insurance including pension insurance, unemployment insurance, work-related injury insurance and medical insurance for our employees. We do not maintain property insurance to protect our equipment and other properties essential to our business operation against risks and unexpected events. We do not maintain business interruption insurance or general third-party liability insurance, nor do we maintain product liability insurance or “key person” insurance. We consider our insurance coverage sufficient and in line with market practice for our business operations in China.

LEGAL PROCEEDINGS

We are currently not a party to material legal or administrative 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. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Operations—Allegations or lawsuits against us or our management may harm our reputation and business.”

REGULATIONS

PRC Regulations

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business and operations.

Major Regulatory Authorities Related to Our Business in the PRC

The National Health Commission of the PRC, or the NHC, formerly known as National Health and Family Planning Commission, or the NHFPC, is responsible for, among others, formulating and implementing regulations relating to medical institutions, medical services and medical technologies. In particular, the medical test laboratories and clinical gene amplification test laboratories established for genomic testing services, and the medical technologies used in genomic testing services are under supervision of the NHC.

The National Medical Products Administration, or the NMPA, under and supervised by the State Administration for Market Regulation of the PRC, or the SAMR, was established to undertake part of duties of the former China Food and Drug Administration, or the CFDA. The NMPA is responsible for, among others, formulating and implementing regulations relating to research, manufacturing, operation, distribution, quality control, usage and registration of medical devices. In-vitro diagnostic reagents, gene sequencers or software relating to genomic testing services shall be deemed as medical devices and supervised by the NMPA and its local counterparts.

The Ministry of Science and Technology of the PRC, or MOST is responsible for regulating the collection, preservation, utilization and outbound provision of human genetic resources.

Regulations Related to Laboratories

Medical Test Laboratories

According to the Administrative Regulations on Medical Institutions, promulgated by the State Council, effective on September 1, 1994, last amended on March 31, 2022 and effective from May 1, 2022, and the Implementation Measures of the Administrative Regulations on Medical Institutions, effective on September 1, 1994, last amended by the NHFPC and effective from April 1, 2017, establishment of certain types of medical institutions, including medical test laboratory and hospital, will be subject to approval of the NHC of its local counterparts, and such medical institution shall be registered for practice and obtain a medical institution practicing license before it carries out diagnosis and treatment activities. Medical institutions can, after obtaining the medical institution practicing license, within their respective registered diagnosis scope, provide diagnosis and treatment services.

According to the Basic Standards and Practice of Medical Test Laboratory, promulgated by the NHFPC and effective from July 20, 2016, a medical test laboratory, which conducts clinical tests, including clinical hematology tests and body fluid tests, clinical chemistry tests, clinical immunology tests, clinical microbiology tests, clinical molecular cytogenetic tests and clinical pathology tests, for the purpose of diagnosis, management, prevention or treatment of diseases and health assessment, shall be regulated as a medical institution. The establishment and operation of a medical test laboratory shall apply for an approval from NHC or its local counterparts to obtain a medical institution practicing license. As of the date of this annual report, we had established four medical test laboratories in China and obtained the medical institution practicing license.

The Interim Administrative Measures on Clinical Laboratories, which was promulgated by the Medical Treatment Team of Joint Prevention and Control Mechanism against COVID-19 of the State Council and came into force from August 1, 2020, regulates institutional management, quality management, safety, prevention and control of infection, personnel training, among others, for medical test laboratories. Medical test laboratories should establish and operate a quality management system for medical test following the requirements of the Administrative Measures on Clinical Laboratories of Medical Institutions, which was promulgated by the NHC on February 27, 2006, came into effect on June 1, 2006, and amended on July 10, 2020, and using Accreditation Criteria for the Quality and Competence of Medical Laboratories, or ISO 15189, as reference, and shall participate in inter-departmental quality evaluation activities for medical testing at the provincial level and above. Medical test laboratories should obtain the approval from competent authorities for carrying out special testing items such as gene amplification.

Clinical Gene Amplification Test Laboratories

Pursuant to the Administrative Measures for Clinical Gene Amplification Test Laboratories of Medical Institutions, promulgated by the Ministry of Health, a predecessor of the NHC, and effective from December 6, 2010, provincial counterparts of the NHC are responsible for the supervision and administration of clinical gene amplification test laboratories of medical institutions. A clinical gene amplification test laboratory must register its clinical testing items in accordance with the Catalogue of Clinical Laboratory Items for Medical Institutions, or the Testing Items Catalog, with the relevant provincial counterpart of the NHC after passing the technical verification. If a clinical gene amplification test laboratory performs any clinical testing items that exceed the scope of clinical test items registered with the NHC, or if any clinical testing reagents it uses for clinical gene amplification tests are not registered with the NMPA, such laboratory may be required to suspend its business of clinical gene amplification testing. In addition, pursuant to the Notice on Issues Related to the Management of Clinical Laboratory Items, or Circular 167, promulgated by the NHFPC on February 25, 2016, the clinical testing items which are not included in the Testing Items Catalog, but with clear clinical significance, relatively high specificity and sensitivity, and reasonable price, shall be validated in time to meet clinical needs.

Pathogenic Microorganism Laboratories

Pursuant to the Regulations on Administration of Biosafety in Pathogenic Microorganism Laboratories, promulgated by the State Council, effective on November 12, 2004, and last amended on March 19, 2018, pathogenic microorganism laboratories are classified into four levels, namely Biosafety Levels 1 to 4, in terms of biosafety protection levels in accordance with national standards on biosafety of laboratories. Laboratories at Biosafety Levels 1 and 2 are prohibited from engaging in laboratory activities related to highly pathogenic microorganisms. The construction, alternation or expansion of a laboratory at Biosafety Level 1 or 2 are required to be filed for record with the local counterparts of NHC. The entity launched a pathogenic microorganism laboratory must develop a scientific and strict management system, regularly inspect the implementation of the regulations on biosafety, and regularly inspect, maintain and update the facilities, equipment and materials in the laboratory, to ensure its compliance with the national standards. As of the date of this annual report, we have completed the record-filings of our four laboratories for the purposes of carrying out laboratory activities related to pathogenic microorganism.

Regulations Related to Medical Technologies

Pursuant to the Administration Measures for the Clinical Application of Medical Technologies, promulgated by the NHC on August 13, 2018 and effective from November 1, 2018, clinical application of medical technologies will be classified as “restricted” or “prohibited” under a negative list. Medical institutions are prohibited from engaging in the clinical application of any medical technologies that fall within the “prohibited” category, and medical institutions that engage in the clinical application of any medical technologies that fall within the “restricted” category are required to file with the NHC or its relevant local counterpart within fifteen business days after they perform the first clinical application of such technologies. In addition, pursuant to the Notice of Strengthening the Administration of Products and Technologies Relating to Clinical Gene Sequencing, or Notice No. 25, jointly promulgated by the General Office of the NHFPC and the General Office of the CFDA on February 9, 2014, medical institutions are prohibited from applying gene sequencing technologies or products for clinical use before the issuance of relevant access standards and management regulations.

Regulations Related to Medical Devices

The manufacturing, using and operation of medical devices in China are subject to extensive regulations. Pursuant to the Regulations on the Supervision and Administration of Medical Devices, promulgated by the State Council and last amended on February 9, 2021 and effective from June 1, 2021, or the 2021 Medical Devices Regulation, and the Administrative Measures for In-vitro Diagnostic Reagents, promulgated by CFDA and effective from October 1, 2014 and last amended on August 26, 2021 and effective from October 1, 2021, medical devices, including *in vitro* diagnostic reagents, are classified into three different categories, namely Class I, II and III, based on their respective degrees of risk. Class I medical devices refer to such devices with low level of risk, the safety and effectiveness of which can be ensured through routine administration. Class II medical devices refer to such devices with medium level of risk, the safety and effectiveness of which must be strictly controlled. Class III medical devices refer to such devices with high level of risk, the safety and effectiveness of which must be guaranteed and be subject to strict control through special administrative measures. Pursuant to Notice No. 25, gene sequencing diagnostic products, including gene sequencers and relevant diagnostic reagents and software, will be regulated as medical devices.

Compared with the previously promulgated medical devices regulations, the major amendments in the 2021 Medical Devices Regulations are as follows: (i) implementing the registrant-or-submitter accountability systems to highlight the entity responsibilities of enterprises; (ii) improving the system for medical device innovation; (iii) optimizing the approval process and filing process; (iv) improving post-marketing regulatory requirements; and (v) reinforcing penalty and punishment. In addition, pursuant to the 2021 Medical Devices Regulation, for *in vitro* reagents, qualified medical institutions are allowed to develop reagents in-house and use such self-developed unregistered reagents for their own use under the guidance of licensed physicians, if there are no such type of registered reagents otherwise approved for marketing in China. The NMPA and the NHC are authorized to jointly promulgate more detailed regulations in this regard.

For the registrant-or-submitter accountability systems, the 2021 Medical Devices Regulations stipulates that enterprises or research institutions required to obtain a medical device registration certificate or undergo medical device filings are the registrants or submitters, and they are legally responsible for the safety and effectiveness of their medical devices when developing, producing, operating and using the medical devices; it also enunciates the obligations of registrants or submitters and requires that registrants or submitters should establish and maintain a quality management system effectively, conduct post-marketing research and risk control, adverse event monitoring and re-evaluation, establish and implement a system to trace and recall products, among others. The 2021 Medical Devices Regulations clarifies the rights and duties of registrants or submitters as well as other market entities, and specifies the obligations of entrusted manufacturers, e-commerce platform operators, users and other entities.

Registration and Filing of Medical Devices

The Administrative Measures for Registration and Record-Filing of Medical Devices was promulgated by NMPA, became effective from October 1, 2021 and replaced the Administrative Measures for Registration of Medical Devices. According to the Administrative Measures for Registration and Record-Filing of Medical Devices, Class I medical devices are subject to record-filing with the local counterparts of the NMPA at the city level; Class II medical devices are subject to the inspection, approval and obtaining the registration certificates from the relevant provincial counterpart of the NMPA; and Class III medical devices are subject to the inspection, approval and obtaining the registration certificate from the NMPA. The medical device registration certificate is valid for five years, and the holder should apply for the renewal of such registration certificate within six months prior to its expiration. We have obtained the medical device registration certificates from the NMPA or its provincial counterparts for three assays and four platforms as of the date of this annual report.

Under the current PRC legal regime, clinical trials are not required for the record-filing of the Class I medical devices, but are prerequisite for the application for the registration of the Class II and Class III medical devices. However, medical devices may be exempted from clinical trials under any of the following circumstances: (i) the medical device has clear working mechanisms, finalized design and mature manufacturing processes, and the medical devices of the same type that are available on the market have been used in clinical application for years without records of any serious adverse events, and the medical device will not change the general purposes; (ii) the safety and effectiveness of such medical devices can be proved through non-clinical evaluation; or (iii) the safety and effectiveness of such medical devices can be proved through the analysis and evaluation of the data obtained from the clinical trials or clinical application of the same categories of medical devices.

Production Permit and GMP for Medical Devices

Pursuant to the 2021 Medical Devices Regulation and the Administrative Measures for Production of Medical Devices, promulgated by the CFDA, amended and effective from November 17, 2017, an entity engaging in the production of Class I medical devices must complete record-filing with the local counterpart of the NMPA at city level where such entity is located, and an entity engaging in the production of Class II or Class III medical devices must obtain a production permit of medical devices from the NMPA at provincial level. The production permit of medical devices is valid for five years and the holder need to apply for the extension of such permit within six months prior to its expiration.

According to the Good Manufacturing Practice of Medical Devices promulgated by the CFDA and effective from March 1, 2015, an entity engaging in the design, developing, production, sales after-sales of medical devices must establish and effectively maintain quality control standards.

Operation Permit and GSP for Medical Devices

Pursuant to the 2021 Medical Devices Regulation and the Administrative Measures for Operation of Medical Devices, promulgated by the CFDA, and amended and effective from November 17, 2017, an entity engaging in the operation of Class I medical devices is not required to obtain approval or filing for record with the NMPA or its local counterparts; an entity engaging in the operation of Class II medical devices is required to file for record with the local counterpart of NMPA at city level where such entity is located; and an entity engaging in the operation of Class III medical devices is required to apply for an operation permit from the local counterpart of the NMPA at city level. The operation permit of medical devices is valid for five years and the holder need to apply for the extension of such permit within six months prior to its expiration. According to the 2021 Medical Devices Regulation, entities are prohibited from selling or using any medical devices that have not been properly registered or filed with the NMPA or its relevant local counterpart for record.

Pursuant to the Good Sales Practice of Medical Devices promulgated by the CFDA and effective from December 12, 2014, an entity engaging in the procurement, acceptance, preservation, sales, transportation and after-sales of medical devices must take effectively quality control measures.

Regulations Related to Export of Medical Devices or Medical Supplies

Pursuant to the Administrative Measures for Production of Medical Devices, an entity engaging in the production of medical devices for export must complete record-filing of such medical devices with the local counterpart of the NMPA at city level and must ensure that such medical devices for export meet the relevant requirements of the import country or region.

In addition, according to the Notice of China Food and Drug Administration on the Promulgation of the Administrative Regulations on the Certificate of Free Sale for Medical Device Exportation, which was issued by the CFDA on June 1, 2015, the relevant CFDA will issue a certificate of free sale for medical device exportation to a production enterprise which has obtained a registration certificate and a production permit of medical devices in China or has completed the filing procedures for the registration and production of medical devices. The production enterprise should ensure that the products for exportation meet the requirements of relevant regulations on the exportation of medical devices and relevant requirements of the importing country. All legal liabilities arising in the course of exportation will be borne by the production enterprise itself.

In accordance with the Notice of Strengthening the Export Quality Supervision of Medical Supplies for Anti-Epidemic which was jointly promulgated by Ministry of Commerce, or “MOFCOM”, General Administration of Customs and SAMR on April 25, 2020 and became effective on April 26, 2020, entities engaging in the export of medical supplies for anti-epidemic, including but not limited to reagents and materials used to perform COVID-19 testing, which has obtained certification or registration of foreign standard, must submit a written declaration that such medical supplies for export have met the quality standard and safety requirements of the import country or region. In addition, customs will check and release such medical supplies of manufacturing enterprises that have obtained certification or registration of foreign standards based on the list provided by MOFCOM, and we were approved to be enrolled in such list.

Regulations Related to Encouragement of Innovation in Medical Devices

There are certain laws, regulations and policies for encouraging innovation in medical devices in China. Pursuant to the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform on the System for Review and Approval to Encourage Innovation of Drugs and Medical Devices which was issued on October 8, 2017, in order to encourage the research and development of innovative medical devices, priority processing will be given to the review and approval of those innovative medical devices that are supported by the National Science and Technology Major Projects, the National Key Research and Development, and the clinical trials carried out and recognized by the National Clinical Medical Research Center.

Pursuant to the Special Procedures for Examination and Approval of Innovative Medical Devices which were promulgated on November 2, 2018 and became effective on December 1, 2018, special procedures will be applicable to the examination and approval for medical devices in the following circumstances: (i) the applicant legally owns the invention patent of the core technology of the product through its technological innovation activities in the PRC, or legally obtains the invention patent or the right of use thereof through transfer in the PRC, and the interval between the date of application for the special examination and approval of innovative medical devices and the date of publication of the patent grant should not exceed five years; or the patent administration department of the State Council has published 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 that the core technology solution of the product possesses novelty and inventiveness; (ii) the applicant has developed the prototype product and completed the preliminary research under a true and controllable process that generated complete and traceable data; (iii) the product (a) has major working mechanism or mechanism of action which is the first of its kind in the PRC, (b) has fundamental improvement in product performance or safety compared with similar products, (c) is of an internationally leading standard in terms of techniques and has significant clinical value.

The Center for Medical Device Evaluation of the NMPA will give prioritize the technical review of innovative medical devices upon receiving the registration application, and thereafter the NMPA will prioritize the administration approval of such medical devices.

Regulations Related to Human Genetic Resources

The Regulation for the Administration of Human Genetic Resources, or the HGR Regulation, promulgated by the State Council on May 28, 2019 and effective from July 1, 2019, regulates entities engaging in collection, preservation, utilization and outbound provision of human genetic resources. Human genetic resources include (i) human genetic resources materials, such as organs, tissues and cells that contain hereditary substances such as human genomes genes, and (ii) human genetic resources information, such as data generated from human genetic resources.

According to the HGR Regulation, collection and preservation of human substances such as organs, tissues and cells and carrying out related activities for the purposes of clinical diagnosis and treatment, blood collection and supply services, crime investigation, doping detection and funeral and interment will be subject to other applicable laws and regulations.

Pursuant to the HGR Regulation, foreign entities, individuals and such entities established or actually controlled thereby, each, a Restricted Entity, are prohibited from collecting or preserving human genetic resources of China within the territory of the PRC, nor provide human genetic resources of China outward across the border; while a Restricted Entity is allowed to conduct scientific research activities by utilizing human genetic resources of China through cooperation with scientific research institutions, higher education institutions, medical institutions or enterprises of China, each, a Domestic Entity. The utilization of human genetic resources of China in any international cooperative scientific research is subject to approval by MOST. However, if human genetic resources of China are utilized for international cooperative clinical trials without any outbound provision of human genetic resources, the approval described above is not required. Instead, the Domestic Entity is required to file for record with MOST for the purpose of obtaining product registration of relevant medicine and medical device in China.

The Biosecurity Law of the PRC promulgated by the SCNPC on October 17, 2020 and became effective on April 15, 2021, establishes a comprehensive legislative framework for the pre-existing regulations in areas such as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbial laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. It stipulates that the clinical research of new biomedical technologies is subject to ethical review and should be conducted in the medical institutions with corresponding qualifications and the operation of human clinical research should be conducted by the professional medical workers with corresponding qualifications. It stipulates further that the collection, preservation, utilization and external provision of human genetic resources of China are required to comply with ethical principles and should not endanger public health, national security and public interests.

Regulations Related to Product Quality and Consumer Protection

Product Quality

Pursuant to the Product Quality Law of the PRC, which was promulgated by the SCNPC on February 22, 1993, last amended and became effective on December 29, 2018, a manufacturer is liable for the quality of products that it produces. The quality of a product must be inspected and proved to be conformed to the standards. Industrial products which may be hazardous to health or safety of human life and property are required to comply with national and industrial standards safeguarding the health and safety of human life and property. In the absence of such national or industrial standards, such products shall meet the requirements for procuring the protection of health and safety of human life and property.

According to the Product Quality Law of the PRC, consumers or other victims who suffer personal injury or property losses due to product defects may demand compensation from the manufacturer as well as the seller. Where the responsibility for product defects lies with the manufacturer, the seller shall, after settling compensation, have the right to recover such compensation from the manufacturer, and vice versa.

Pursuant to the PRC Civil Code which was promulgated by the National People's Congress on May 28, 2020 and became effective from January 1, 2021, manufacturers will assume tort liability if the defects in relevant products cause damage to others. Sellers will assume tort liability if the defects in relevant products causing damage to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage.

Consumer Protection

Pursuant to the Consumer Protection Law of the PRC which was promulgated by the SCNPC on October 31, 1993, last amended on October 25, 2013 and became effective on March 15, 2014, the rights and interests of the consumers who buy or use commodities or receive services for the purposes of daily consumption should be protected, and all manufacturers and sellers involved should ensure that the products and services provided will not cause damage to the customers. Violations of the Consumer Protection Law of the PRC may result in the imposition of fines. In addition, manufacturers and sellers may be ordered to suspend operations and their business license may be revoked, while criminal liability may be imposed in serious cases.

Regulations Related to Intellectual Property

China is a signatory to several major international conventions on intellectual property rights, including the Agreement on Trade-Related Aspects of Intellectual Property Rights, Paris Convention for the Protection of Industrial Property, Berne Convention for the Protection of Literary and Artistic Works, World Intellectual Property Organization Copyright Treaty, Madrid Agreement Concerning the International Registration of Marks and Patent Cooperation Treaty.

Patent Law

According to the Patent Law of the PRC, or the Patent Law, promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and effective from June 1, 2021, and the Implementation Rules of the Patent Law of the PRC, promulgated by the State Council on June 15, 2001 and last amended on January 9, 2010, the CNIPA is responsible for administering patents in the PRC. The Patent Law and its implementation rules provide for three types of patent, namely invention, utility model and design. The protection period is 20 years for inventions, 10 years for utility models and 15 years for designs, commencing from their respective application dates. The PRC patent system follows the “first come, first file” principle, i.e., where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first. To be patentable, an invention or a utility model must meet three criteria: novelty, inventiveness and practicability. Except under certain specific circumstances provided by law, any third-party user must obtain consent or a proper license from the patent owner to use the patent. Otherwise, the use of constitutes an infringement of the patent rights, and must pay compensation to the patentee and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, will be held criminally liable in accordance with the law.

In addition to the above, under the HGR Regulation, any patent right derived from international cooperative scientific research concerning genetic resources of China should be jointly owned by both Domestic Entity and Foreign Entity engaging in such international cooperative scientific research.

Trademark Law

Trademarks are protected by the Trademark Law of the PRC, or the Trademark Law, promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and effective from November 1, 2019, as well as the Implementation Regulation of the Trademark Law of the PRC adopted by the State Council on August 3, 2002 and last amended on April 29, 2014. In China, registered trademarks include commodity trademarks, service trademarks, collective trademarks and certification trademarks.

The Trademark Office under the CNIPA is responsible for registrations and administration of trademarks. The period of validity for a registered trademark is ten years, commencing from the date of registration. Upon expiry of the period of validity, the registrant must go through the formalities for renewal within twelve months prior to the date of expiry as required, if the registrant needs to continue to use the trademark. As with patents, a “first come, first file” principle has been followed in China with respect to the trademark registration pursuant to the Trademark Law. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case will be timely referred to a judicial authority and decided according to law.

Copyright Law

Pursuant to the Copyright Law of the PRC, or the Copyright Law, which was promulgated on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and the Implementation Regulation of the Copyright Law of the PRC, which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013, Chinese citizens, legal persons, or other organizations shall, enjoy copyright in their published and unpublished works, which include works of literature, art, natural science, engineering technology and computer software.

Domain Names

Domain names are protected under the Administrative Measures on Internet Domain Name, which was promulgated by the Ministry of Industry and Information Technology, or the MIIT, on August 24, 2017 and became effective from November 1, 2017. Domain names are registered through domain name service agencies that are organized pursuant to relevant regulations, and applicants will become domain name holders upon successful registration.

Regulations Related to Information Security and Data Privacy

Pursuant to the PRC Civil Code, which was promulgated by the National People's Congress, or the NPC, on May 28, 2020 and became effective on January 1, 2021, and the Personal Information Protection Law, which was promulgated on August 20, 2021 and became effective on November 1, 2021, the personal information of a natural person must be legally protected. An information processor is prohibited from disclosing or tampering with any personal information collected or stored thereby; and without the consent of the natural person, no personal information can be illegally provided to any other person, excluding the information through which the specific individual cannot be identified after processing and which cannot be restored. An information processor is required to take technical measures and other necessary measures to ensure the security of the personal information collected and stored thereby and prevent any information leakage, tampering, and loss.

The Interpretations on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens' Personal Information was jointly released by the Supreme People's Court and the Supreme People's Procuratorate on May 8, 2017 and became effective on June 1, 2017. Several concepts regarding the crime of "infringement of citizens' personal information" stipulated by Article 253A of the Criminal Law of the PRC, including the "provision of citizens' personal information" and "illegally obtaining any citizen's personal information by other methods," were clarified, and the standards for determining "serious circumstances" and "particularly serious circumstances" of this crime were also specified thereunder.

Pursuant to the Regulations for Medical Institutions on Medical Records Management, jointly promulgated by the NHFPC and National Administration of Traditional Chinese Medicine on November 20, 2013, and effective from January 1, 2014, medical institutions and medical practitioners must strictly protect the privacy information of patients, and any leakage of patients' medical records for non-medical, non-teaching or non-research purposes is prohibited. The Administrative Measures for Population Health Information (On Trial) promulgated by the NHFPC on May 5, 2014, stipulates that medical service providers collecting or using population healthcare information must guarantee the information security and protect individual privacy.

The Data Security Law of the PRC, or the Data Security Law, was promulgated by the SCNPC on June 10, 2021 and became effective on September 1, 2021, which establishes a tiered system for data protection in terms of their importance, and data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, are required to be treated with higher level of protection. Specifically, the Data Security Law provides that operators that processing "important data" are required to appoint a "data security officer" and a "management department" to take charge of data security. If any company violates the Data Security Law and transfers "important data" outside China, it may be punished by administration sanctions, including penalties, fines, and/or suspension of relevant business or revocation of the business license.

The Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law, was issued by the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council on July 6, 2021. These opinions require (i) speeding up the revision of legislation on strengthening the confidentiality and archives coordination between regulators related to overseas issuance and listing of securities, and (ii) improving the legislation on data security, cross-border data flow, and management of confidential information.

On October 29, 2021, the Cyberspace Administration of China, or the CAC, published the Measures on Security Assessment of Cross-border Transfer of Data (Draft for Comments), pursuant to which data processors should make self-assessment of the risks before making cross-border data transfer, and apply for security assessment for cross-border data transfer in any of the following circumstances: (i) transferring the personal information and “important data” collected and produced by “critical information infrastructure operators,” or CIIOs; (ii) the contemplated cross-border data transfer involves “important data”; (iii) transferring personal information cross-border by personal information processors which process more than one million individuals’ personal information; (iv) transferring more than one hundred thousand individuals’ personal information or more than ten thousand individuals’ sensitive personal information cumulatively; or (v) other circumstances which require the application for cross-border data transfer security assessment as determined by the CAC.

On November 14, 2021, the CAC published the Regulations on Network Data Security Management (Draft for Comment), or the Draft Data Security Regulations, which sets forth, among other things, detailed cybersecurity review standards for listing in Hong Kong and abroad, protection of “important data” and personal information rights, and the security of cross-border data transmission. According to the Draft Data Security Regulations, “data processors” refer to individuals and organizations that independently determine the purposes of and methods of processing in their data processing activities. If the listing of a data processor’s securities in Hong Kong affects or may affect national security, or if a data processor engages in other data processing activities that affect or may affect national security, the data processor is required to apply for cybersecurity review in accordance with relevant provisions.

The Measures for Cybersecurity Review was promulgated by the CAC and several other administrations in December 2021 and became effective in February 2022. According to the Measures for Cybersecurity Review, (i) the purchase of network products and services by a CIIO and the data processing activities of a “network platform operator” that affect or may affect national security will be subject to the cybersecurity review; (ii) if a “network platform operator” who possesses personal information of more than one million users intends to go public in a foreign country, it must apply for a cybersecurity review with the Cybersecurity Review Office; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if they determine certain network products, services or data processing activities affect or may affect national security.

Regulations Related to Advertisement

Pursuant to the Advertisement Law of the PRC, which was promulgated by SCNPC on October 27, 1994, last amended and became effective from April 29, 2021, advertisements should not contain false statements or be deceitful or misleading to consumers. Advertisements that are subject to censorship, including advertisements relating to pharmaceuticals and medical devices, will be reviewed by relevant authorities in accordance with applicable rules before being distributed by broadcasting, movies, television, newspapers, journals or otherwise. The Advertisement Law of the PRC further stipulates that advertisements for medical treatment, pharmaceutical products or medical devices should not contain: (i) any assertion or guarantee for efficacy and safety; (ii) any statement on cure rate or effectiveness rate; (iii) any comparison with the efficacy and safety of other pharmaceutical products or medical devices or with other healthcare institutions; (iv) any use of endorsements or testimonials; or (v) other items as prohibited by laws and regulations.

Pursuant to the Interim Measures for the Administration of Internet Advertisement, which was promulgated by the SAMR on July 4, 2016 and became effective as of September 1, 2016, the Internet advertisement should be identifiable and clearly identified as an “advertisement.” Advertisement of any medical treatment, medicines, foods for special medical purpose, medical apparatuses, pesticides, veterinary medicines, dietary supplement or other special commodities or services shall not be released unless it has passed the required review by advertisement regulating authorities.

Pursuant to the Measures for Administration of Medical Advertisement which was jointly promulgated by the SAMR and the Ministry of Health on November 10, 2006 and became effective on January 1, 2007, medical advertisements are subject to review by relevant health authorities and a medical advertisement examination certificate is required to be obtained before the relevant medical advertisements are released. The medical advertisement examination certificate is valid for one year and may be renewed upon application.

Pursuant to the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose promulgated by the SAMR on December 24, 2019 and effective from March 1, 2020, no advertisement for any drug, medical device, dietary supplement or food for special medical purpose may be published without censorship. The SAMR will be responsible for organizing and guiding the censorship of advertisements for drugs, medical devices, dietary supplements and foods for special medical purpose. Departments for market regulation and drug administration of provinces, autonomous regions and municipalities directly under the central government are responsible for the censorship of advertisements for drugs, medical devices, dietary supplements and foods for special medical purpose and may legally entrust other administrative authorities with specifically carrying out advertisement censorship. Advertisements for drugs, medical devices, dietary supplements and foods for special medical purpose should be authentic and legal, and not contain any false or misleading content.

Pursuant to the Measures Regarding the Administration of Drug Information Service through the Internet, which was promulgated by the CFDA, last amended and became effective from November 17, 2017, the Internet drug information services, referring to that of providing medical information (including medical devices information) services to Internet users through the Internet, are classified into two categories, namely, profit-making services and non-profit services. Any website intending to provide drug information services through Internet, should be approved by the provincial counterparts of the NMPA before applying for an operation permit or record-filing from the authority in charge of information industry under the State Council or the administration of telecommunication at the provincial level.

Regulations Related to Environment Protection

Pursuant to the Environmental Protection Law of the PRC which was promulgated by the SCNPC on December 26, 1989, amended on April 24, 2014 and became effective on January 1, 2015, all enterprises and institutions that discharge pollutants are required to take measures to prevent and control pollution and damage to the environment from waste gas, waste water, waste residues, medical waste, dust, malodorous gases, radioactive substances, noise, vibration, ray radiation and electromagnetic radiation generated in the course of production, construction or other activities. Pollution prevention and control facilities of a construction project must be simultaneously designed, constructed and put into operation with the principal part of the construction project. Enterprises that manufacture, store, transport, sell, use or dispose of chemicals and materials containing radioactive substances are required to comply with the relevant PRC regulations to prevent environmental pollution. The relevant authorities are authorized to impose various types of penalties on the persons or entities in violation of the environmental regulations, including fines, restriction or suspension of operation, shut-down, detention of office-in-charge, among others.

Regulations Related to Anti-Bribery

According to the Anti-Unfair Competition Law of the PRC promulgated by the SCNPC on September 2, 1993 and last amended on April 23, 2019, and the Interim Provisions on the Prohibition of Commercial Bribery promulgated by the State Administration for Industry and Commerce on November 15, 1996, business operators are prohibited from providing or making any promise to provide economic benefits, including cash, other property or otherwise, to the transaction counterpart or any third party that may be able to influence the transaction, for the purposes of enticing such party to secure a transaction opportunity or a competitive advantages for such business operator. Any breach of the relevant anti-bribery rules described above may subject the business operator to administrative punishment or criminal liability, depending on the seriousness of the cases.

Regulations Related to Labor

The main PRC employment laws and regulations include the Labor Law of the PRC, or the Labor Law, promulgated by the SCNPC and last amended on December 29, 2018, the Labor Contract Law of the PRC, or the Labor Contract Law, promulgated by the SCNPC and last amended on December 28, 2012 and became effective from July 1, 2013, and the Implementing Regulations of the Labor Contract Law of the PRC promulgated by the State Council on September 18, 2008. Pursuant to the Labor Law and the Labor Contract Law, employers are required to establish and improve labor rules and regulations according to the laws and regulations and strictly comply with the national standards, provide trainings to their employees, protect their labor rights and perform their labor obligations. Employers are required to execute written labor contracts with full-time employees. Labor contracts are categorized into labor contracts with fixed term, labor contracts without fixed term and labor contracts to be expired upon completion of certain tasks. All employers must comply with local minimum wage standards. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

In addition, according to the PRC Social Insurance Law promulgated by the SCNPC on October 28, 2010, amended and came into effect on December 29, 2018 and the Regulations on the Administration of Housing Funds amended by the State Council and came into effect on March 24, 2019 and the Provisional Regulations on Collection and Payment of Social Insurance Premiums amended by the State Council and came into effect on March 24, 2019, employers in China are required to pay premium for basic pension insurance, unemployment insurance, maternity insurance, work injury insurance, basic medical insurance and housing funds for its employees at the applicable rates based on the amounts stipulated by the laws. Any employer that fails to pay required amount of premium to local administrative authorities on time or in full may be required to settle the overdue amount or subject to fine.

Regulations of Foreign Investment

On March 15, 2019, the NPC promulgated the Foreign Investment Law, which became effective on January 1, 2020 and replaced the trio of existing laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law. The existing foreign-invested enterprises established prior to the effective of the Foreign Investment Law may keep their corporate forms within five years.

Pursuant to the Foreign Investment Law, “foreign investors” refer to natural person, enterprise, or other organization of a foreign country, “foreign-invested enterprises,” or FIEs, refer to any enterprise established under PRC law that are wholly or partially invested by foreign investors, and “foreign investment” refer to any foreign investor’s direct or indirect investment in mainland China, including (i) establishing FIEs in mainland China either individually or jointly with other investors; (ii) obtaining stock shares, stock equity, property shares, other similar interests in Chinese domestic enterprises; (iii) investing in new projects in mainland China either individually or jointly with other investors; and (iv) making investment through other means provided by laws, administrative regulations, or State Council provisions.

Based on the Foreign Investment Law and its implementing rules, China adopts a system of pre-entry national treatment and “negative list” with respect to foreign investment administration. The “negative list” will be proposed by the competent investment department of the State Council in conjunction with the competent commerce department of the State Council and other relevant departments, and be reported to the State Council for promulgation, or be promulgated by the competent investment department or competent commerce department of the State Council after being reported to the State Council for approval.

Foreign investments that are beyond the “negative list” will be granted national treatment. Foreign investors are prohibited from investing in any prohibited industries that are specified in the “negative list,” while foreign investment can invest in the restricted industries by satisfying relevant conditions stipulated in the “negative list.” The current industry entry clearance requirements governing investment activities in the PRC by foreign investors are set out in two categories, namely the Special Administrative Measures (Negative List) (2021 version) for Foreign Investment Access, last amended and jointly promulgated by the MOFCOM and the NDRC on December 27, 2021 and became effective as of January 1, 2022, or the Negative List, and the Encouraged Industry Catalogue for Foreign Investment (2020 version). Industries not listed in these two categories are generally deemed “permitted” for foreign investment unless otherwise restricted by other PRC laws. Development and application of gene diagnosis and treatment technology is prohibited to foreign investment pursuant to the Negative List. According to the Negative List, the overseas offering and listing of a domestic enterprise that operates in business falling into the category which foreign investors are prohibited to invest will be subject to review by the government authority. Pursuant to the press conference held by NDRC on January 18, 2022, the foresaid review shall not be applicable to the domestic enterprises that seek to offer and list securities in overseas markets indirectly.

On December 30, 2019, the MOFCOM and the SAMR, jointly promulgated the Measures for Information Reporting on Foreign Investment, which became effective on January 1, 2020. Pursuant to the measures, where a foreign investor directly or indirectly carries out investment activities in China, the foreign investor or the foreign-invested enterprise is required to submit the investment related information to the competent commerce authority for further handling.

The Interim Provisions on Investment Made by Foreign-Invested Enterprises in the PRC, jointly promulgated by the MOFCOM and the SAMR on July 25, 2000 and amended on October 28, 2015, stipulates that, FIEs are not permitted to invest in any sector that is prohibited from any foreign investments. Where an FIE makes investment in a restricted sector, the foreign invested enterprise must file an application with the provincial commercial department of the place where the investee company is located. The relevant company registration authority will, in accordance with the relevant provisions of the Company Law and the Regulations on the Administration of Company Registration of the People's Republic of China, determine whether to approve the registration or not. If the registration is approved, a Business License of an Enterprise Legal Person will be issued with the designation "Invested by a Foreign-Invested Enterprise" added. FIEs are required to report the establishment of the investee company within 30 days of the date of their establishments to the original examination and approval authority for record-filing.

Regulations Related to Tax

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC, which was promulgated the NPC on March 16, 2007 and last amended and effective on December 29, 2018, and the Regulations for the Implementation of the Law on Enterprise Income Tax, which was promulgated by the State Council, and amended on April 23, 2019, collectively the EIT Law, generally impose a uniform enterprise income tax rate of 25% on all resident enterprises in China, including FIEs. The EIT Law permits certain High and New Technologies Enterprises, to enjoy a reduced 15% enterprise income tax rate if they meet certain criteria and are officially acknowledged.

PRC Value Added Tax

On March 23, 2016, the MOFCOM and the State Administration of Taxation, or the SAT, jointly issued the Circular on the Pilot Program for Overall Implementation of the Collection of Value Added Tax Instead of Business Tax, or Circular 36, which became effective on May 1, 2016. Pursuant to the Circular 36, all companies operating in construction, real estate, finance, modern service or other sectors that were required to pay business tax are instead required to pay value-added tax, or VAT, in lieu of business tax. A VAT rate of 6% applies to revenue derived from the provision of certain services. Unlike business tax, a taxpayer is allowed to offset the qualified input VAT paid on taxable purchases against the output VAT chargeable on the revenue from services provided.

On March 20, 2019, MOFCOM, the SAT and the General Administration of Customs issued the Announcement on Policies for Deepening the VAT Reform, or Announcement 39, which became effective on April 1, 2019, to further slash VAT rates. According to the Announcement 39, (i) the 16% or 10% VAT rates previously imposed on sales and imports by general VAT taxpayers are reduced to 13% or 9%, respectively; (ii) the 10% purchase VAT credit rate allowed for the procured agricultural products is reduced to 9%; (iii) the 13% purchase VAT credit rate allowed for the agricultural products procured for production or commissioned processing is reduced to 10%; and (iv) the 16% or 10% export VAT refund rates previously granted to the exportation of goods or labor services are reduced to 13% or 9%, respectively.

Dividend Withholding Tax

Pursuant to the EIT Law, if a non-resident enterprise has not set up an organization or establishment in the PRC, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion With Respect to Tax on Income, the withholding tax rate in respect to the payment of dividends by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise.

Pursuant to the Notice of the SAT on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, promulgated by the SAT in February 2009, a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced withholding tax: (i) it should be a company as provided in the tax treaty; (ii) it must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (iii) it must have directly owned such percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends.

In October 2019, the SAT promulgated the Administrative Measures for Non-Resident Taxpayers to Enjoy Treatments under Tax Treaties, or SAT Circular 35, which became effective in January 2020. SAT Circular 35 provides that non-resident enterprises are not required to obtain pre-approval from the relevant tax authority in order to enjoy the reduced withholding tax rate. Instead, non-resident enterprises and their withholding agents may, by self-assessment and on confirmation that the prescribed criteria to enjoy the tax treaty benefits are met, directly apply the reduced withholding tax rate, and file necessary forms and supporting documents when performing tax filings, which will be subject to post-tax filing examinations by the relevant tax authorities.

If our Hong Kong subsidiary satisfies all the requirements under the tax arrangement and receives approval from the relevant tax authority, the dividends paid to the Hong Kong subsidiary would be subject to withholding tax at the standard rate of 5%.

Income Tax for Share Transfers

According to the Public Notice Regarding Certain Enterprise Income Tax Matters on Indirect Transfer of Properties by Non-resident Enterprise, or SAT Bulletin 7, promulgated by the SAT in February 2015, if a non-resident enterprise transfers the equity interests of a PRC resident enterprise indirectly by transfer of the equity interests of an offshore holding company (other than a purchase and sale of shares in public securities market) without a reasonable commercial purpose, the PRC tax authorities have the power to reassess the nature of the transaction and the indirect equity transfer will be treated as a direct transfer. As a result, the gain derived from such transfer, which means the equity transfer price less the cost of equity, will be subject to PRC withholding tax at a rate of up to 10%. In October 2017, the SAT issued the Announcement on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or the SAT Bulletin 37, which, among others, repeals certain rules stipulated in SAT Bulletin 7 and became effective on December 1, 2017. The SAT Bulletin 37 further details and clarifies the tax withholding methods in respect of income of non-resident enterprises.

Regulations Related to Dividend Distribution

Under our current corporate structure, our Cayman Islands holding company may rely on dividend payments from our PRC Subsidiaries, which is a foreign invested enterprise incorporated in China, to fund any cash and financing requirements we may have. The principal legislation with respect to payment or distribution of dividends by foreign invested enterprises include (i) the Company Law of the PRC, amended by the SCNPC in October 2018, and (2) the Foreign Investment Law and its implementation rules. Under these laws, foreign invested enterprises in the PRC may pay dividends only out of accumulated profits, after setting aside annually at least 10% of accumulated after-tax profits as reserve fund, if any, unless these reserves have reached 50% of the registered capital of the enterprises. These reserve funds may not be distributed as cash dividends. A foreign invested enterprise may allocate a portion of its after-tax profits to its employee welfare and bonus funds at its discretion. Profit of a foreign invested enterprise shall not be distributed before the losses thereof for the previous accounting years have been made up. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Regulations Related to Import and Export of Goods

Pursuant to the Customs Law of the PRC, which was promulgated by the SCNPC on January 22, 1987, last amended and became effective on April 29, 2021, the import of goods throughout the period from the time of arrival in the territory of China to the time of customs clearance, the export of goods throughout the period from the time of declaration to the customs to the time of departure from the territory of China, and the transit, transshipment and through-shipment goods throughout the period from the time of arrival in the territory of China to the time of departure from the territory of China shall be subject to customs control.

Pursuant to the Foreign Trade Law of the PRC, which was promulgated by the SCNPC on May 12, 1994, last amended and became effective on November 7, 2016, any foreign trade business operator that is engaged in the import and export of goods or technology are required to register with the administrative authority of foreign trade of the State Council or the institution entrusted thereby for record purposes, unless it is otherwise provided for by any law, administrative regulation or the foreign trade department of the State Council. Where any foreign trade business operator that fails to file for archival registration according to relevant provisions, the customs may not handle the procedures of customs declarations and release of the import or export goods.

Pursuant to the Administrative Provisions on the Record-filing of Customs Declaration Entities of the PRC, which was promulgated by the General Administration of Customs on November 19, 2021, and became effective on January 1, 2022, the customs declaration entities refer to the consignor or consignee of imported and exported goods and the customs declaration enterprise, and the customs declaration entities may handle their own customs declarations within the customs territory of PRC.

Regulations Related to Foreign Exchange

Foreign Currency Exchange

The PRC Foreign Exchange Administration Regulations, or the Foreign Exchange Administration Regulations, promulgated by the State Council on January 29, 1996 and last amended on August 5, 2008, governs the foreign currency exchange in China. Under the Foreign Exchange Administration Regulations, Renminbi is generally freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China, unless prior approval of SAFE or its local counterparts has been obtained.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Direct Investment, as amended, which substantially amends and simplifies the foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible previously. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, as amended, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing issued by the SAFE on December 26, 2014, domestic companies are required to register the overseas listed with the foreign exchange control bureau located at its registered address in 15 business days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund should be consistent with the contents of the document and other public disclosure documents.

On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies, or SAFE Notice 13, according to which, entities and individuals may apply for such foreign exchange registrations from qualified banks. The qualified banks, under the supervision of SAFE, may directly review the applications and conduct the registration.

On March 30, 2015, SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise, or Circular 19, which became effective on June 1, 2015. According to Circular 19, the foreign exchange capital of FIEs will be subject to the Discretionary Foreign Exchange Settlement, which means that the foreign exchange capital in the capital account of a foreign-invested enterprise for which the rights and interests of monetary contribution have been confirmed by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operational needs of the foreign-invested enterprise, and if a foreign-invested enterprise needs to make further payment from such account, it still needs to provide supporting documents and proceed with the review process with the banks. Furthermore, Circular 19 stipulates that the use of capital by FIEs should follow the principles of authenticity and self-use within the business scope of enterprises. The capital of a foreign-invested enterprise and capital in Renminbi obtained by the foreign-invested enterprise from foreign exchange settlement shall not be used for the following purposes: (i) directly or indirectly used for payments beyond the business scope of the enterprises or payments as prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities unless otherwise provided by the relevant laws and regulations; (iii) directly or indirectly used for granting entrust loans in Renminbi (unless permitted by the scope of business), repaying inter-enterprise borrowings (including advances by the third-party) or repaying the bank loans in Renminbi that have been sub-lent to third parties; or (iv) directly or indirectly used for expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

The Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or Circular 16, was promulgated by SAFE and became effective on June 9, 2016. Pursuant to the Circular 16, enterprises registered in the PRC may also convert their foreign debts from foreign currency to Renminbi at their discretion. 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, and such converted Renminbi is prohibited from being provided as loans to its non-affiliated entities.

On January 26, 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimizing Genuineness and Compliance Verification, or Circular 3, which stipulates several capital control measures with respect to the outbound remittance of profit from domestic entities to offshore entities, including (i) under the principle of genuine transaction, banks must check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities must hold income to account for previous years' losses before remitting the profits. Moreover, pursuant to Circular 3, domestic entities must make detailed explanations of the sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

In October 2019, the SAFE promulgated the Notice for Further Advancing the Facilitation of Cross-border Trade and Investment, or the SAFE Circular 28, which, among other things, allows all FIEs to use Renminbi converted from foreign currency denominated capital for equity investments in China, as long as the equity investment is genuine, does not violate applicable laws, and complies with the negative list on foreign investment. The Circular Regarding Further Optimizing the Cross-border RMB Policy to Support the Stabilization of Foreign Trade and Foreign Investment, which was jointly promulgated by the People's Bank of China, NDRC, MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the China Banking and Insurance Regulatory Commission and SAFE on December 31, 2020 and became effective on February 4, 2021, allows the non-investment FIEs to make domestic reinvestment with RMB capital in accordance with the law on the premise that they comply with prevailing regulations and the invested projects in China are authentic and compliant. In addition, if an FIE uses RMB income under capital accounts to conduct domestic reinvestment, the invested enterprise is not required to open a special deposit account for RMB capital.

On April 10, 2020 the SAFE issued the Notice of SAFE on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business, or the SAFE Circular 8. The SAFE Circular 8 provides that under the condition that the use of the funds is genuine and compliant with current administrative provisions on use of capital relating to capital account, enterprises are allowed to use capital under capital account such as capital funds, foreign debts and overseas listings for domestic payment, without submission to the bank prior to each transaction of materials evidencing the veracity of such payment.

Foreign Exchange Registration of Overseas Investment by PRC Resident

On July 4, 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Administration on Domestic Residents' Overseas Investment, Financing and Roundtrip Investment via Special Purpose Vehicles, or SAFE Circular 37, which replaced the former circular commonly known as "SAFE Circular 75" promulgated by SAFE on October 21, 2005. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiaries of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Furthermore, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls.

Share Option Rules

Under the Administration Measures on Individual Foreign Exchange Control issued by the People's Bank of China on December 25, 2006, all foreign exchange matters involved in employee share ownership plans and share option plans in which PRC citizens participate require approval from SAFE or its authorized branch. Pursuant to SAFE Circular 37, PRC residents who participate in share incentive plans in overseas non-publicly-listed companies may submit applications to SAFE or its local branches for the foreign exchange registration with respect to offshore special purpose companies.

Pursuant to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participation in Equity Incentive Plans of Overseas Listed Companies promulgated by SAFE on February 15, 2012, or SAFE Circular 7, PRC residents who are granted shares or share options by companies listed on overseas stock exchanges under share incentive plans are required to (i) register with SAFE or its local branches, (ii) retain a qualified PRC agent, which may be a PRC subsidiary of the overseas listed company or another qualified institution selected by the PRC subsidiary, to conduct SAFE registration and other procedures with respect to the share incentive plans on behalf of the participants, and (iii) retain an overseas institution to handle matters in connection with their exercise of share options, purchase and sale of shares or interests and funds transfers.

United States Regulations

Federal and State Laboratory Licensing Requirements

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of or assessment of health. CLIA requires that a laboratory hold a certificate applicable to the type of laboratory examinations it performs and that it complies with, among other things, standards covering operations, personnel, facilities administration, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. Because our laboratory in China is a CAP accredited laboratory, CMS does not perform this survey and inspection and relies on our CAP survey and inspection. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory that is certified as "high complexity" under CLIA may develop, manufacture, validate and use proprietary tests referred to as laboratory developed tests, or LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to any testing we perform may change over time and any such changes could have a material effect on our business.

CLIA provides that a state may also adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. For example, state laws may require that nonresident laboratories, or out-of-state laboratories, maintain an in-state laboratory license to perform tests on samples from patients who reside in that state. As a condition of state licensure, these state laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures or facility requirements or prescribe record maintenance requirements. Because our U.S. laboratory is located in the State of Maryland, we are required to maintain a Maryland state laboratory license. We maintain a current license with Maryland Department of Health for our Maryland laboratory, although we currently do not perform any commercial diagnostic testing. Other states may currently have or adopt similar licensure requirements in the future, which may require us to modify, delay or stop its operations in those states.

Failure to comply with CLIA certification and state clinical laboratory licensure requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity.

CLIA and state laws and regulations, operating together, sometimes limit the ability of laboratories to offer consumer-initiated testing (also known as “direct access testing”). CLIA certified laboratories are permitted to perform testing only upon the order of an “authorized person,” defined as an individual authorized under state law to order tests or receive test results, or both. Many states do not permit persons other than licensed healthcare providers to order tests. We currently do not offer direct access testing and our CLIA tests may only be ordered by authorized healthcare providers.

Regulatory Framework for Medical Devices in the United States

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA has jurisdiction over medical devices, which are defined to include, among other things, IVDs. The FDA regulates, among other things, the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval (PMA). Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device Classification

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III, depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient, of which the safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the FDA’s quality system regulation (“QSR”) facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I devices are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and special controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. As part of the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA’s satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. A PMA application must also provide valid scientific evidence that demonstrates to the FDA’s satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Investigational Device Exemption (IDE) Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE once certain requirements are addressed and institutional review board, or IRB, approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin only after the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA’s approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product’s safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA’s IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Such clinical trials must also comply with the FDA’s good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- side effects or device malfunctions of similar products already in the market that change the FDA’s view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- IRB and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports of sponsors of clinical investigations;

- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that our trial designs are unreliable or inadequate to demonstrate safety and efficacy.

The 510(k) Clearance Process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is “substantially equivalent” to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within

90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not “substantially equivalent” to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous pre-marketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. The *de novo* classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. *De novo* classification may also be available after receipt of a “not substantially equivalent” letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. Many minor modifications are accomplished by a letter-to-file in which the manufacturer documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer’s determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

In addition, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

In September 2019, the FDA finalized guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

The PMA Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided and may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee’s recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA’s satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support changes from the device covered by a PMA and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

FDA Regulation of Laboratory Developed Tests

Although the FDA regulates medical devices, including IVDs, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDCA and FDA regulations with respect to LDTs, which are a subset of IVDs that are intended for clinical use and are developed, validated and offered within a single laboratory for use only in that laboratory.

Legislative and administrative proposals addressing oversight of LDTs were introduced in recent years and we expect that new legislative and administrative proposals will be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our LDTs or to develop and introduce new tests as LDTs. For example, in 2014 the FDA issued two draft guidance documents proposing a risk-based framework with respect to applying the FDA's oversight over LDTs. The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, we believe the FDA planned to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. In November 2016, the FDA announced its intention not to finalize the 2014 draft guidance to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution. In January 2017, the FDA issued a discussion paper on possible approaches to LDT regulation.

Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, the FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs.

The FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements.

Research Use Only or Investigational Use Only Devices

A research use only (“RUO”) device is an IVD that is in the laboratory research phase of development. RUO devices must bear prominent labeling stating: “For Research Use Only. Not for use in diagnostic procedures.” An IUD device is an IVD that is in the product testing phase of development. An IUD device must bear prominent labeling stating: “For Investigational Use Only. The performance characteristics of this product have not been established.” Neither RUO or IUD devices may be used in clinical practice, nor can such devices be advertised or promoted for clinical or diagnostic purposes. Devices that are intended for RUO or IUD and are properly labeled as RUO or IUD are exempt from compliance with the FDA requirements discussed above, including the approval or clearance and QSR requirements. A device labeled RUO or IUD but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDCA and is subject to FDA enforcement activities. The FDA may consider the totality of the circumstances surrounding distribution and use of an RUO or IUD device, including how the device is marketed, when determining its intended use.

EAP (Expedited Access Program)/Breakthrough Devices Program

The EAP was a voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to premarket submissions. Under the EAP, the FDA worked with device sponsors to try to reduce the time and cost from development to marketing decision without changing the FDA’s PMA standard of reasonable assurance of safety and effectiveness or any other standards of valid scientific evidence. Components of the EAP include priority review, more interactive review, senior management involvement, and assignment of a case manager.

Pursuant to the 21st Century Cures Act, the breakthrough devices provisions were added to the FDCA. The breakthrough devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. For breakthrough devices, the FDA intends to provide interactive and timely communication with the sponsor during device development and throughout the review process. FDA also intends to assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing expectations applicable to the investigational use of a breakthrough device. In addition, all submissions for devices designated as breakthrough devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. The breakthrough devices program superseded the EAP and the previous priority review program for medical device submissions. The FDA has indicated that all participants previously granted EAP designation will have designation as breakthrough devices, and that no separate action will be necessary for sponsors of EAP-designated devices to receive breakthrough device designation for such devices.

In September 2020, we received breakthrough device designation from the FDA for our HCCscreen™ for “the qualitative detection of hepatocellular carcinoma (HCC)-associated DNA mutations and methylated DNA in cell-free DNA (cfDNA), and protein biomarkers derived from peripheral blood specimens,” and “is intended for early detection of HCC in individuals who are designated to be at high-risk for hepatocellular carcinoma due to chronic HBV infection and/or liver cirrhosis.”

Emergency Use Authorization

In addition to the 510(k) clearance, PMA, and *de novo* classification pathways to market, the Commissioner of the FDA, under delegated authority from the Secretary of Health and Human Services (“HHS”) may, under certain circumstances in connection with a declared public health emergency, allow for the marketing of a product that does not otherwise comply with FDA regulations by issuing an EUA for such products.

Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of the Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological or nuclear agent or agents;
- a determination by the Secretary of DoD that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
- a determination by the Secretary of HHS of a public health emergency that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

On February 4, 2020, the Secretary of HHS determined that the novel coronavirus presented a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus that causes COVID-19.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a disease attributable to the agents described above, that the product's potential benefits outweigh its potential risks and that there is no adequate, approved alternative to the product.

Potential alternative products may be unavailable if there are insufficient supplies to meet the emergency need. FDA may establish additional conditions on an EUA that are necessary to protect public health, including conditions related to information that must be disseminated to health care providers and patients, the monitoring and reporting of adverse events, and record keeping. Conditions may also relate to how a product is distributed and administered and how a product is advertised. Importantly, EUAs are not full marketing approvals. Rather, EUAs are only effective for the period of time the public health emergency declaration is in effect. Full approval of the product under applicable standards established under the FDCA would be necessary to continue to distribute the product absent an EUA. EUAs may also be revised or revoked by FDA at any time.

In June 2020, we received an EUA for Genetron SARS-CoV-2 RNA Test for “qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as oropharyngeal, nasopharyngeal, anterior nasal and mid-turbinate nasal swab specimens) from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.”

Companion Diagnostics

Companion diagnostics are regulated by the FDA as medical devices. The FDA issued a final guidance document in July 2014 addressing agency policy in relation to in vitro companion diagnostic tests. The guidance explains that for some drugs and therapeutic biologics, the use of a companion diagnostic test is essential for the safe and effective use of the product, such as when the use of a product is limited to a specific patient subpopulation that can be identified by using the test. According to the guidance, the FDA generally requires the therapeutic product and the companion diagnostic to be developed and approved or cleared contemporaneously. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and in vitro companion diagnostic device on issues related to co-development of the products, and in December 2018, FDA issued a draft guidance describing considerations for the development and labeling of in vitro companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products.

Pervasive and Continuing FDA regulation

After a device enters commercial distribution, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval of product modifications, or the potential for new 510(k) clearances for certain modifications to 510(k)-cleared devices;

- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions such as: warning letters, fines, injunctions, consent decrees and civil penalties; unanticipated expenditures, repair, replacement, refunds, recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; the FDA's refusal of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products; the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries; and withdrawing 510(k) clearance or premarket approvals that have already been granted and criminal prosecution.

U.S. Healthcare Fraud and Abuse Laws

In the U.S., we are subject to a number of federal and state healthcare regulatory laws that apply to clinical laboratories, including, but are not limited to, federal and state anti-kickback, false claims, self-referral and other healthcare fraud and abuse laws.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Anti-Kickback Statute includes statutory exceptions and regulatory safe harbors that protect certain arrangements. Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances, including the parties' intent and the arrangement's potential for abuse, and may be subject to greater scrutiny by enforcement agencies.

The Stark Law generally prohibits a physician who has a financial relationship, or who has an immediate family member who has a financial relationship, with entities providing designated health services, or DHS, from referring Medicare and Medicaid patients to such entities for the furnishing of DHS, unless an exception applies. The Stark Law also prohibits the entity from billing for any such prohibited referral. The definition of DHS under the Stark Law includes clinical laboratory services. Unlike the federal Anti-Kickback Statute, the Stark Law is violated if the financial arrangement does not meet an applicable exception, regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral.

The Federal False Claims Act, or FCA, prohibits a person from knowingly presenting, or caused to be presented, a false or fraudulent request for payment from the federal government, or from making a false statement or using a false record to have a claim approved. The federal FCA further provides that a lawsuit thereunder may be initiated in the name of the United States by an individual, a “whistleblower,” who is an original source of the allegations. Moreover, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute or the Stark Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Penalties for a violation of the FCA include fines for each false claim, plus up to three times the amount of damages caused by each false claim.

Further, the Civil Monetary Penalties Statute authorizes the imposition of civil monetary penalties, assessments and exclusion against an individual or entity based on a variety of prohibited conduct, including, but not limited to offering remuneration to a federal health care program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive health care items or services from a particular provider.

HIPAA also established federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

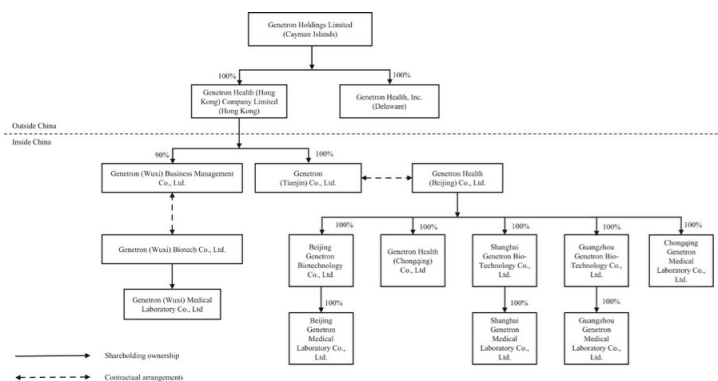
The Physician Payments Sunshine Act, among other things, requires manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by the statute) and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

Several states, including the state we operate, have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payor, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program.

Violation of any of these laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement, fines, additional reporting requirements and compliance oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/or imprisonment.

4.C. Organizational Structure

The following diagram illustrates our corporate structure as of the date of this annual report, including our material subsidiaries and VIEs:



Contractual Arrangements with the VIEs and their Shareholders

Investment in the field of technology development and applications relating to human stem cells and genomic diagnosis and treatment is a prohibited category for foreign investment in the PRC. Precision oncology services fall within the scope of such prohibited category. Therefore, we established the VIEs, Genetron Health (Beijing) Co., Ltd. ("Genetron Health"), and Genetron (Wuxi) Biotech Co., Ltd., to conduct precision oncology services business activities. We exercise effective control over Genetron Health through contractual arrangements among Genetron (Tianjin) Co., Ltd., Genetron Health and its shareholders; and we exercise effective control over Genetron (Wuxi) Biotech Co., Ltd. through contractual arrangements among Genetron (Wuxi) Business Management Co., Ltd, Genetron (Wuxi) Biotech Co., Ltd. and its shareholders.

These contractual arrangements allow us to:

- exercise effective control over the VIEs;
- receive substantially all of the economic benefits of the VIEs; and
- have an exclusive option to purchase all or part of the equity interest in and/or assets of the VIEs when and to the extent permitted by laws.

As a result of these contractual arrangements, we are the primary beneficiary of the VIEs and, therefore, have consolidated the financial results of the VIEs in our consolidated financial statements in accordance with IFRS.

In the opinion of Shihui Partners, our PRC legal counsel:

- the ownership structures of the VIEs, currently do not, and will not result in any violation of the applicable PRC laws or regulations currently in effect; and

- the contractual arrangements among the PRC Subsidiaries, the VIEs and their shareholders, are governed by PRC laws or regulations, and are currently valid, binding and enforceable in accordance with the applicable PRC laws or regulations currently in effect, and do not result in any violation of the applicable PRC laws or regulations currently in effect.

However, our PRC legal counsel has also advised us that there are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules. In particular, in March 2019, the National People's Congress of the PRC adopted the Foreign Investment Law, which became effective on January 1, 2020. Among other things, the Foreign Investment Law defines the "foreign investment" as investment activities in China by foreign investors in a direct or indirect manner, including those circumstances explicitly listed thereunder as establishing new projects or foreign invested enterprises or acquiring shares of enterprises in China, and other approaches of investment as stipulated by laws, administrative regulations or otherwise regulated by the State Council. The Foreign Investment Law leaves uncertainty as to whether foreign investors' controlling PRC onshore variable interest entities via contractual arrangements will be recognized as "foreign investment" and thus be subject to the restrictions/prohibitions on foreign investments. Accordingly, the PRC regulatory authorities may take a view that is contrary to the opinion of our PRC legal counsel.

The following is a summary of the contractual arrangements by and among the PRC Subsidiaries, the VIEs and the shareholders of the VIEs and their spouses, as applicable. For the complete text of these contractual arrangements, please see the copies filed as exhibits incorporated into this annual report. For a more detailed description of the risks related to these contractual arrangements and our corporate structure, please see "Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Corporate Structure."

Agreements that Provide us with Effective Control over the VIEs

Shareholder Voting Rights Entrustment Agreements. Pursuant to (i) the Shareholder Voting Rights Entrustment Agreement dated July 30, 2019 among Genetron (Tianjin) Co., Ltd., Genetron Health and its shareholders, and (ii) the Shareholder Voting Rights Entrustment Agreement dated December 7, 2020 among Genetron (Wuxi) Business Management Co., Ltd., Genetron (Wuxi) Biotech Co., Ltd. and its shareholders, these shareholders irrevocably authorize the respective PRC Subsidiaries to act as his or her attorney-in-fact to exercise all of his or her rights as a shareholder of the respective VIE, including, but not limited to, the right to call and attend shareholders' meetings, execute and deliver any and all written resolutions and meeting minutes as a shareholder, vote by itself or by proxy on any matters discussed on shareholders' meetings, sell, transfer, pledge or dispose of any or all of the shares, nominate, appoint or remove the directors, supervisors and senior management, and other shareholders rights conferred by the articles of association of such VIE and the relevant laws and regulations. Each of these agreements shall terminate once (i) either of the PRC Subsidiaries directly holds the entire assets of the respective VIE, and such PRC Subsidiary is allowed to conduct the business of the respective VIE under the then PRC laws, or (ii) either of the PRC Subsidiaries is registered as the sole shareholder of the respective VIE, and such PRC Subsidiary is allowed to conduct the business of the respective VIE under the then PRC laws. The shareholders shall not have the right to terminate these agreements or revoke the appointment of the attorney-in-fact without the prior written consent of the respective PRC Subsidiary.

Spousal Consent Letters. The spouse of each of Mr. Sizhen Wang, Mrs. Xiaoge Wang, Mrs. Shuyan Wei and Mr. Yuchen Jiao has signed a spousal consent letter. Under the spousal consent letter, the spouse unconditionally and irrevocably waives any rights or entitlements whatsoever to such shares that may be granted to his/her pursuant to applicable laws and undertakes not to make any assertion of rights to such shares. The spouse agrees and undertakes that he/she will take all necessary actions to ensure the proper performance of the contractual arrangements, and will be bound by the contractual arrangements in case he/she obtains any equity of respective VIE due to any reason.

Equity Interest Pledge Agreements. Pursuant to (i) the Equity Interest Pledge Agreement dated July 30, 2019 among Genetron (Tianjin) Co., Ltd. and its shareholders and (ii) the Equity Interest Pledge Agreement dated December 7, 2020 among Genetron (Wuxi) Business Management Co., Ltd., Genetron (Wuxi) Biotech Co., Ltd. and its shareholders, the shareholders of VIEs have pledged 100% equity interest in VIEs in favor of PRC Subsidiaries to guarantee the performance by VIEs and their shareholders of their obligations under the Exclusive Business Cooperation Agreements, the Exclusive Option Agreements and any other agreements to be executed among our PRC Subsidiaries, the VIEs and their shareholders from time to time. If VIEs or their respective shareholders breach their contractual obligations under these agreements, the respective PRC Subsidiary, as pledgee, will have the right to dispose of the pledged shares entirely or partially. The shareholders of VIEs also agreed, without the respective PRC Subsidiary's prior written consent, not to transfer the pledged shares, establish or permit the existence of any security interest or other encumbrance on the pledged shares, or dispose of the pledged shares by any other means, except by the performance of the Exclusive Option Agreements. We have completed the registration of the pledge of equity interests in VIEs with the relevant office of Administration for Industry and Commerce in accordance with applicable PRC laws.

Agreements that Allow us to Receive Economic Benefits from the VIEs

Exclusive Business Cooperation Agreements. Pursuant to (i) the Exclusive Business Cooperation Agreement dated July 2, 2019 between Genetron (Tianjin) Co., Ltd. and Genetron Health and (ii) the Exclusive Business Cooperation Agreement dated December 7, 2020 between Genetron (Wuxi) Business Management Co., Ltd. and Genetron (Wuxi) Biotech Co., Ltd., the respective PRC Subsidiary has the exclusive right to provide the respective VIE with technical support, business support and consulting services in return for fees equal to 100% of the consolidated net profits of such VIE. Without the PRC Subsidiaries' prior written consents, the respective VIE shall not, directly and indirectly, obtain the same or similar services as provided under these agreements from any third party, or enter into any similar agreement with any third party. The PRC Subsidiaries have the right to determine the service fee charged to the respective VIE under these agreements by considering, among other things, the complexity of the services, the time spent by employees of the PRC Subsidiaries to provide the services, contents and commercial value of the service provided, as well as the benchmark price of similar services in the market. The PRC Subsidiaries will have the exclusive ownership of all intellectual property rights developed by performance of these agreements. Each of the Exclusive Business Cooperation Agreements will remain effective until it is terminated at the discretion of the respective PRC Subsidiary or upon the transfer of all the shares of such VIE to the respective PRC Subsidiary.

Agreements that Provide us with the Option to Purchase the Equity Interests in the VIEs

Exclusive Option Agreements. Pursuant to (i) the Exclusive Option Agreement dated July 30, 2019 among Genetron (Tianjin) Co., Ltd., Genetron Health and its shareholders and (ii) the Exclusive Option Agreement dated December 7, 2020 among Genetron (Wuxi) Business Management Co., Ltd., Genetron (Wuxi) Biotech Co., Ltd. and its shareholders, the shareholders of VIEs irrevocably granted the PRC Subsidiaries an exclusive option to purchase all or part of their equity interests in such VIEs at the lowest price permitted by applicable PRC laws. Those shareholders further undertake that they will neither allow the encumbrance of any security interest in such VIEs, except for the pledge created pursuant to the Equity Interest Pledge Agreements, nor transfer, mortgage or otherwise dispose of their legal or beneficial interests in VIEs without the prior written consent of the respective PRC Subsidiary, and will cause the shareholders' meeting and/or the board of directors and/or the executive directors of VIEs not to approve such proposal. Each of these agreements will remain effective until it is terminated at the discretion of the respective PRC Subsidiary or upon the transfer of all the equity interest in such VIEs to the respective PRC Subsidiary.

4.D. Property, Plants and Equipment

We are headquartered in Beijing, China and have material offices and clinical laboratories in Shanghai, Chongqing, Guangzhou, Tianjin, China and Maryland, USA. As of December 31, 2021, we had leased office space, plants and clinical laboratories for our material facilities. We lease our premises under operating lease agreements from independent third parties. See "Item 4. Information on the Company—4.B. Business Overview—Property and Facilities."

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this annual report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those we describe under “Item 3. Key Information—3.D. Risk Factors” and elsewhere in this annual report.

5.A. Operating Results**Key Factors Affecting Our Results of Operations***General Factors Affecting Our Results of Operations*

Our business and results of operations are affected by a number of general factors, including:

- global macroeconomic environment, especially China’s overall economic growth;
- technology development and commercialization of precision oncology industry;
- changes in regulations over China’s precision oncology industry; and
- market acceptance of precision oncology services and products.

Unfavorable changes in any of these general factors could materially and adversely affect our business and results of operations. In addition, our results of operations have been, and are expected to continue to be, affected by a number of specific factors, many of which may be beyond our control. A discussion of the key factors is set out below.

*Specific Factors Affecting Our Results of Operations**Increased adoption of our precision oncology services and products*

Our revenue growth is mainly driven by our ability to increase the adoption of our precision oncology testing in the form of LDT services, including diagnosis and monitoring and early screening, and in the form of IVD products. In 2019, 2020 and 2021, we sold approximately 22,900, 21,900 and 24,360 LDT diagnostic tests, respectively. In particular, we sold approximately 5,100, 6,840, 6,540 and 5,880 LDT diagnostic tests in the first, second, third and fourth quarters of 2021, respectively. Our revenue generated from provision of LDT services increased by 24.4% from RMB234.6 million in 2019 to RMB291.7 million in 2020, and further increased by 15.8% to RMB337.8 million (US\$53.0 million) in 2021. As of December 31, 2021, we had entered into contracts with 58 hospitals, including in-hospital IVD product purchase agreements with 30 hospitals. Our revenue generated from sales of IVD products increased by 169.2% from RMB34.9 million in 2019 to RMB94.0 million in 2020 and further increased by 64.4% to RMB154.5 million (US\$24.3 million) in 2021.

The results of our operations will largely depend on our ability to attract both individual customers and institutional clients, as well as retain and broaden adoption with existing institutional clients. Because our technology is relatively novel to customers in China, we have established a strong sales and marketing team to provide doctors, patients and other clients with the customized support. We especially focus on developing our partnership with KOLs and specialists in local hospitals to promote and raise awareness of the clinical application of precision oncology among physicians and patients.

Comprehensive offerings for broadening monetization channels

We continuously review market demands in precision oncology medicine industry, so we can strategically develop and expand our services and our full-cycle cancer management products. For our diagnosis and monitoring services, we have developed LDT services covering CGP panels, and focused gene panels to address different needs across the top ten major cancer types in China. We have also launched LDT services detecting minimal residual disease (“MRD”) in hematologic cancer with Seq-MRD method. Furthermore, we have entered early cancer screening market with LDT services to capture the long-term potential for early cancer screening targeting asymptomatic individuals who are at a higher risk of developing cancer and individuals who are generally concerned with cancer risks. We are also a pioneer in IVD registration for both platforms and assays. In addition to our NMPA-approved IVD platforms and assays, we are developing other IVD assays to further diversify our IVD products offerings. In addition, we provide development services to, such as co-development of CDx with, leading global and domestic biopharmaceutical companies and monetize capacity of our high-throughput sequencing platforms to provide research services and sequencing services, including provision of genomic sequencing services to peer companies and institutions. We believe our comprehensive services and products will effectively address market demands and therefore drive our revenue growth.

Investment in technology and product innovation to support commercial growth

Investment in research and development, advancement in technology and development of new products are critical to establish and maintain our industry leading position. We have developed innovative technologies since our inception, including Genetron One-Step Seq™ Method, ctDNA low frequency mutations detection technology and Mutation Capsule™ technology. We conduct adequate and well-controlled trials to collect scalable data to support the development of our technologies. Those core technologies form the foundation on which we develop new products and services, and our pipeline products are expected to drive our future growth. We plan to allocate more resources to develop and market our new services and products, especially our LDT services to capture the long-term potential for early cancer screening, our LDT services detecting MRD in hematologic cancer and our research and sequencing capabilities. We expect to increase our research and development expenses with the goal of fueling further innovation, and the outcomes of our continued investment may have a significant impact on the results of our operations.

Obtaining regulatory approval for our pipeline products

There is an increasing demand from hospitals for the provision of one-stop IVD genomic testing services as the concept of precision oncology wins gradual acceptance among physicians. Adoption by public hospitals and insurance coverage often requires registration from the NMPA—each IVD product must be registered in association with a specific sequencing platform. Companies with NMPA-registered IVD products and platforms are expected to win larger market shares. We have an experienced regulatory team dedicated in handling regulatory approval for our pipeline IVD products and platforms. As of December 31, 2021, we had an in-depth IVD pipeline of seven assays, covering both diagnosis and monitoring services and early screening services. We believe once we obtain NMPA registrations for our pipeline products, we will gain significant advantage compared to our peers and therefore, achieve future growth and create new revenue drivers. We believe our leadership and experience in obtaining regulatory approvals of our pipeline products will be the foundation to further achieve economies of scale. In contrast, any failure to obtain regulatory approval for our pipeline products may cause adverse impact on the results of our operations.

Expanding collaboration with biopharmaceutical company customers

We intend to pursue further growth in our collaboration with biopharmaceutical companies. Our revenue and business opportunities depend in part on our ability to attract new biopharmaceutical company customers and to maintain and expand relationships with existing biopharmaceutical company customers. We believe our products and services could be used by biopharmaceutical companies for a wide range of applications, including discovery of new targets and mechanisms of acquired resistance, retrospective sample analysis to rapidly identify biomarkers associated with response and lack of response, prospective screening and patient referral to accelerate clinical trial enrollment, and companion diagnostic development to support the approval and commercialization of therapeutics and may become one of our revenue drivers. As of December 31, 2021 we had partnered with 60 biopharmaceutical companies in genomics research and clinical development. We will further optimize our research and development capacities to satisfy the potential demands of existing and new biopharmaceutical company customers.

Managing our costs and expenses effectively

Our ability to manage our costs and expenses efficiently is critical to the success of our business. Our cost of revenue primarily consists of cost of raw materials, labor cost, equipment and infrastructure expenses associated with diagnosis and monitoring and development services. Driven by the greater economies of scale, our cost of revenue as a percentage of revenue decreased from 55.2% in 2019 to 38.7% in 2020, and decreased from 38.7% in 2020 to 36.5% in 2021. We expect our cost of revenue to grow in absolute amount, in line with our business growth. We expect the cost of revenue as a percentage of revenue to remain largely stable. We plan to leverage our growing bargaining power to negotiate favorable pricing with our raw material suppliers, and we expect to be able to utilize infrastructure and manage operations more effectively, both of which will allow us to increase our gross margin.

We incurred operating expenses in sales and marketing, general administration, and research and development activities. In particular, we have historically incurred a substantial amount of selling expenses, which was primarily attributed to our efforts to promote our expanded product and service offerings and expand our market coverage. Such marketing and promotion efforts solidify existing customer relationships and expand our business reach, which in turn is expected to generate more revenue in the long term. We expect our operating expenses to grow in absolute amount, as a result of our continuing investments in sales and marketing, our development of new technologies and innovative products, and additional costs resulting from operating as a public company. We plan to leverage our growing bargaining power to negotiate favorable pricing with our raw material suppliers, and we are able to utilize infrastructure and manage operations more effectively, both of which will allow us to increase our gross margin.

Impact of the COVID-19

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand globally. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. COVID-19 outbreak disrupted the normal life and daily routine of the global population and in amidst of this global pandemic, diagnosis and monitoring and early screening naturally became less a priority as compared to other more imminent health concerns. In addition, due to the continued enforcement of the “zero COVID” strategy in China and the resulting sustained lockdowns and travel restrictions across our major markets in China, the number of cancer patients that visited hospitals we covered decreased. As such, the demand for our precision oncology services and products did not increase as expected, which to certain extent, adversely affected our business operations in 2020 and 2021.

However, the potential impact brought by and the duration of the COVID-19 outbreak is difficult to assess or predict and the full impact of the virus on our operations will depend on many factors beyond our control, including the extent of resurgences of the disease and its variants, vaccine distribution and other actions in response to the virus or to contain its impact. For instance, in addition to the impact on our financial performance, COVID-19 also had temporary negative impact on our business activities, including our HIT Study and advancement of the clinical development and registration of our IVD pipeline products. Our business operations may be further adversely affected if hospitals, our direct sales team, distributors or other business partners continue to be affected by COVID-19. While it is unknown how long these conditions will last and what the complete financial effect will be to our Company, we are closely monitoring the evolving situation and remain focused on executing our strategy in geographies and segments that are less affected by the restrictions. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Operations—We face risks related to health epidemics, including COVID-19, severe weather conditions and other outbreaks.”

Funding for our operations

In 2019, 2020 and 2021, we funded our operations primarily through revenue generated from sales of our services and products, proceeds from equity financing, including our IPO on the Nasdaq, and bank loans. Going forward, with the marketing of our current services and products and the successful commercialization of our pipeline services and products, we expect to fund our operations primarily through revenue generated from sales of our services and products. However, with our business growth and the continuing expansion of our product and service portfolio, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations will affect our cash flow and results of operation.

Key Components of Results of Operations

Revenue

We derive our revenues from (i) diagnosis and monitoring; and (ii) development services.

Our chief operating decision maker has determined that we have three reportable segments, namely (i) diagnosis and monitoring—provision of LDT services, (ii) diagnosis and monitoring—sale of IVD products and (iii) development services.

Diagnosis and monitoring. Diagnosis and monitoring revenue is generated from the provision of precision oncology testing in the form of LDT services, including diagnosis and monitoring and early screening, as well as sales of IVD products.

For LDT services rendered for diagnosis and monitoring service business, we primarily sell LDT services either directly to patients or to hospitals that have entered into testing services agreements with us. For LDT services rendered for early screening business, we retail such tests targeting higher risk population directly or sell such tests to medical examination centers or enterprises to reach a larger customer base. We expect our revenue from LDT services rendered for early screening business to continue to grow. For IVD products sold for diagnosis and monitoring service business, we primarily sell our IVD products either directly to hospitals or through distributors to reach more hospitals.

We expect our revenue from diagnosis and monitoring to increase as a result of our increased brand awareness, further penetration of the market, broader coverage of hospitals, institutions and enterprises, broader adoptions of current IVD products and the registration of our pipeline IVD products.

Development services. Development services revenue is generated from services we provide to biopharmaceutical companies with respect to the development of new drugs and the co-development of CDx, as well as research services we provide to hospitals, colleges and other institutional customers. We expect our development services revenue to increase in line with our expanded collaboration with biopharmaceutical companies.

Cost of Revenue

Our cost of revenue mainly consists primarily of cost of inventories and consumables used, employee benefit expenses, depreciation and amortization, and rental, utilities and office expenses.

Selling Expenses

Our selling expenses primarily consisted of employee benefit expenses for our selling and marketing personnel and promotion expenses from our direct sales. We have devoted significant resources to educate the market, including hosting medical conferences and seminars, promoting awareness, and establishing collaboration with leading KOLs. We expect our selling and marketing expenses to increase in the foreseeable future, as we plan to continue investing substantially in our sales and marketing efforts to expand our sales and marketing team, broaden adoption of our existing services and products, further educate and promote precision oncology market, and promote our pipeline services and products to be launched in the near future.

Administrative Expenses

Our administrative expenses primarily consisted of employee benefit expenses for our management and administrative personnel, rental, utilities and office expenses, depreciation and amortization and professional service fees. We expect that our administrative expenses will continue to increase, primarily due to increased headcount and costs associated with operating as a public company, including expenses related to legal, accounting, maintaining compliance with applicable listing requirements, director and officer insurance premiums and investor relations.

Research and Development Expenses

Our research and development expenses primarily consisted of employee benefit expenses for research and development personnel, cost of inventories and consumables used, rental, utilities and office expenses, depreciation and amortization. These expenses are primarily related to our clinical trials and validation. Research and development costs are expensed as incurred. We expect our research and development expenses to increase in the foreseeable future as we continue to make investments in expanding our technology infrastructure and developing new services and products.

Results of Operations

The following table summarizes our consolidated results of operations both in absolute amounts and as percentages of our revenue from contracts with customers 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 operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	For the Year Ended December 31,					
	2019		2020		2021	
	RMB	%	RMB	%	RMB	US\$
	(in thousands, except for percentages, shares and per share data)					
Revenue	323,425	100.0	424,485	100.0	531,950	83,475
Cost of revenue	(178,435)	(55.2)	(164,268)	(38.7)	(193,983)	(30,440)
Gross profit	144,990	44.8	260,217	61.3	337,967	53,035
Selling expenses	(253,558)	(78.4)	(246,959)	(58.2)	(343,161)	(53,850)
Administrative expenses	(117,169)	(36.2)	(126,318)	(29.8)	(227,001)	(35,622)
Research and development expenses	(91,697)	(28.4)	(148,999)	(35.1)	(253,950)	(39,850)
Net loss allowance for financial and contract assets	(2,733)	(0.8)	(14,843)	(3.5)	(37,032)	(5,811)
Other income and gains—net	13,297	4.1	8,526	2.0	5,329	836
Operating expenses	(451,860)	(139.7)	(528,593)	(124.5)	(855,815)	(134,297)
Operating loss	(306,870)	(94.9)	(268,376)	(63.2)	(517,848)	(81,262)
Finance income	2,483	0.8	28,330	6.7	20,501	3,217
Finance costs	(11,704)	(3.6)	(5,627)	(1.4)	(5,251)	(824)
Finance (costs) / income—net	(9,221)	(2.9)	22,703	5.3	15,250	2,393
Financial Instruments with preferred rights						
—loss on fair value changes	(333,401)	(103.1)	(2,823,370)	(665.1)	—	—
—other losses	(26,542)	(8.2)	—	—	—	—
Loss before income tax	(676,034)	(209.0)	(3,069,043)	(723.0)	(502,598)	(78,869)
Income tax expense	—	—	—	—	—	—
Loss for the year	(676,034)	(209.0)	(3,069,043)	(723.0)	(502,598)	(78,869)
Loss attributable to:						
Owners of the Company	(676,034)	(209.0)	(3,069,043)	(723.0)	(496,238)	(77,871)
Non-controlling interests	—	—	—	—	(6,360)	(998)
	(676,034)	(209.0)	(3,069,043)	(723.0)	(502,598)	(77,869)
Loss per share for loss attributable to owners of the Company						
—Basic and diluted	(5.41)		(10.18)		(1.08)	(0.17)

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Revenue

Our revenue increased by 25.3% from RMB424.5 million in 2020 to RMB532.0 million (US\$83.5 million) in 2021, which was primarily driven by the increase in diagnosis and monitoring revenue.

Diagnosis and monitoring

Our diagnosis and monitoring revenue increased by 27.7% from RMB385.7 million in 2020 to RMB492.4 million (US\$77.3 million) in 2021. The increase was driven by the growth in the revenues generated from both the provision of LDT services and the sale of IVD products. Approximately 24,360 units of LDT diagnostic tests were sold in 2021, representing an increase of 11.2% compared to the number of LDT diagnostic tests sold in 2020. As of December 31, 2020 and 2021, we had entered into contracts with 40 and 58 hospitals, including in-hospital IVD product purchase agreements with 22 and 30 hospitals, respectively.

Our revenue generated from provision of LDT services increased by 15.8% from RMB291.7 million in 2020 to RMB337.8 million (US\$53.0 million) in 2021. Sales of LDT services also included sales of our early screening test, HCCscreen™, which has contributed to our revenue growth in 2021.

Our revenue generated from sales of IVD products increased by 64.4% from RMB94.0 million in 2020 to RMB154.5 million (US\$24.3 million) in 2021. The increase was driven by a growing number of assays and sequencing platforms sold in 2021, notably the Genetron S5 instrument and 8-gene Lung Cancer Assay (Tissue).

Development services

Our revenue generated from development services increased by 2.0% from RMB38.8 million in 2020 to RMB39.6 million (US\$6.2 million) in 2021. The increase was primarily driven by the growth in revenue generated from biopharmaceutical services, partially offset by a decrease in revenue generated from sequencing services.

Cost of revenue

Our cost of revenue increased by 18.1% from RMB164.3 million in 2020 to RMB194.0 million (US\$30.4 million) in 2021, in line with the sales growth of our products and services. The cost of revenue as a percentage of revenue decreased from 38.7% in 2020 to 36.5% in 2021.

Our cost of revenue for diagnosis and monitoring increased by 26.7% from RMB127.2 million in 2020 to RMB161.2 million (US\$25.3 million) in 2021. The increase was attributable to (i) an increase in cost of revenue associated with LDT services from RMB93.5 million in 2020 to RMB106.7 million (US\$16.7 million) in 2021, and (ii) an increase in cost of revenue associated with IVD products from RMB33.7 million in 2020 to RMB54.6 million (US\$8.6 million) in 2021, which in turn was in line with growth of our LDT services rendered and IVD products sold. The cost of revenue for diagnosis and monitoring as a percentage of revenue from diagnosis and monitoring decreased from 33.0% in 2020 to 32.7% in 2021.

Our cost of revenue for development services was RMB37.0 million in 2020, compared to RMB32.8 million (US\$5.1 million) in 2021, representing a decrease of 11.5%. The cost of revenue for development services as a percentage of revenue from development services decreased from 95.4% in 2020 to 82.8% in 2021.

Gross profit and gross profit margin

As a result of the foregoing, our gross profit increased by 29.9% from RMB260.2 million in 2020 to RMB338.0 million (US\$53.0 million) in 2021. In particular, our gross profit for diagnosis and monitoring business increased by 28.1% from RMB258.4 million in 2020 to RMB331.2 million (US\$52.0 million) in 2021.

Our gross profit margin increased from 61.3% in 2020 to 63.5% in 2021. In 2021, gross margin improvements were seen across all major business lines.

Selling expenses

Our selling expenses increased by 39.0% from RMB247.0 million in 2020 to RMB343.2 million (US\$53.9 million) in 2021. The increase was primarily attributable to the expansion of our sales teams.

Administrative expenses

Our administrative expenses increased by 79.7% from RMB126.3 million in 2020 to RMB227.0 million (US\$35.6 million) in 2021. The increase was primarily attributable to higher headcount and professional fees.

Research and development expenses

Our research and development expenses increased by 70.4% from RMB149.0 million in 2020 to RMB254.0 million (US\$39.9 million) in 2021. The increase was mainly attributable to higher R&D headcount and related expenses, as well as our continued efforts in the development of MRD tests, and clinical activities related to early screening and key product such as Onco Panscan.

Net loss allowance for financial and contract assets

Our net loss allowance for financial and contract assets increased significantly from RMB14.8 million in 2020 to RMB37.0 million (US\$5.8 million) in 2021, which was primarily due to the loss allowance for trade receivables and contract assets.

Other income and gains — net

Our other income and gains — net were RMB5.3 million (US\$0.8 million) in 2021, compared to RMB8.5 million in 2020, representing a decrease of RMB3.2 million, or 37.5%, which was primarily attributable to the fair value loss on wealth management products in 2021.

Operating loss

As a result of the foregoing, our operating loss increased by 93.0% from RMB268.4 million in 2020 to RMB517.8 million (US\$81.3 million) in 2021.

Finance income

Our finance income was RMB20.5 million (US\$3.2 million) in 2021, as compared to RMB28.3 million in 2020. The decrease was related to foreign currency exchange fluctuations.

Finance costs

Our finance costs decreased by 6.7% from RMB5.6 million in 2020 to RMB5.3 million (US\$0.8 million) in 2021. The decrease was mainly related to interests on borrowings.

Fair value loss of financial instruments with preferred right

We recorded RMB2,823.4 million and nil fair value loss of financial instruments with preferred right in 2020 and 2021, respectively. The fair value loss of financial instruments with preferred right was primarily in relation to the change of fair value of our preferred shares, which were converted to ordinary shares upon the closing of our IPO on the Nasdaq in June 2020.

Loss for the year

As a result of the foregoing, our loss for the year decreased by 83.7% from RMB3,069.0 million in 2020 to RMB502.6 million (US\$78.9 million) in 2021.

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

See “Item 5. Operating and Financial Review and Prospects—5. A. Operating Results—Year Ended December 31, 2020 Compared to Year Ended December 31, 2019” beginning on page 112 of our Form 20-F for the fiscal year ended December 31, 2020 filed with the SEC on April 9, 2021 (File No.:001-39328) incorporated by reference into this annual report.

Non-IFRS Financial Measures

We use non-IFRS loss and non-IFRS loss per share/ADS for loss attributable to owners of the Company for the year, which are non-IFRS financial measures, in evaluating our operating results and for financial and operational decision-making purposes. We believe that non-IFRS loss and non-IFRS loss per share/ADS for loss attributable to owners of the Company help identify underlying trends in our business that could otherwise be distorted by the effect of certain expenses that we include in our loss for the year. We believe that non-IFRS loss and non-IFRS loss per share/ADS for loss attributable to owners of the Company for the year provide useful information about our results of operations, enhance the overall understanding of our past performance and future prospects and allows for greater visibility with respect to key metrics used by our management in our financial and operational decision-making.

Non-IFRS loss and non-IFRS loss per share/ADS for loss attributable to owners of the Company for the year should not be considered in isolation or construed as an alternative to operating loss, loss for the year or any other measure of performance or as an indicator of our operating performance. Investors are encouraged to review non-IFRS loss and non-IFRS loss per share/ADS for loss attributable to owners of the Company for the year and the reconciliation to their most directly comparable IFRS measures. Non-IFRS loss and non-IFRS loss per share/ADS for loss attributable to owners of the Company for the year presented here may not be comparable to similarly titled measures presented by other companies. Other companies may calculate similarly titled measures differently, limiting their usefulness as comparative measures to our data. We encourage investors and others to review its financial information in its entirety and not rely on a single financial measure.

Non-IFRS loss for the year represents loss for the year excluding share-based compensation expenses and fair value changes of financial instruments with preferred rights and other loss of financial instruments with preferred rights (if applicable). The following table sets forth a reconciliation of non-IFRS net loss to net loss, its most directly comparable IFRS measure, for the years ended December 31, 2019, 2020 and 2021.

	For the Year ended December 31,			
	2019	2020	2021	
	RMB	RMB	RMB	US\$
		(in thousands)		
Loss for the year	(676,034)	(3,069,043)	(502,598)	(78,869)
Adjustments:				
Share-based compensation	35,884	29,951	54,144	8,497
Financial instruments with preferred rights				
-loss on fair value changes	333,401	2,823,370	—	—
-other loss	26,542	—	—	—
Non-IFRS loss	<u>(280,207)</u>	<u>(215,722)</u>	<u>(448,454)</u>	<u>(70,372)</u>

The following table sets forth a reconciliation of non-IFRS net loss per share/ADS to net loss per share for the year, its most directly comparable IFRS measure, for the years ended December 31, 2019, 2020 and 2021.

	For the Year ended December 31,			
	2019	2020	2021	
	RMB	RMB	RMB	US\$
	(in thousands, except for share and per share/ADS data)			
Loss attributable to:				
Owners of the Company	(676,034)	(3,069,043)	(496,238)	(77,871)
Non-IFRS adjustments ⁽¹⁾	395,827	2,853,321	54,144	8,497
Non-IFRS loss attributable to owners of the Company for computing non-IFRS net loss per share/ADS for loss attributable to owners of the Company				
	(280,207)	(215,722)	(442,094)	(69,374)
Share used in IFRS and non IFRS loss per share computation:				
- Basic and diluted	124,894,707	301,379,911	460,547,499	460,547,499
ADS used in IFRS loss per ADS computation:				
- Basic and diluted		60,275,982	92,109,499	92,109,499
Loss per share for loss attributable to owners of the Company				
- Basic and diluted	(5.41)	(10.18)	(1.08)	(0.17)
Loss per ADS (5 ordinary shares equal to 1 ADS) for loss attributable to owners of the Company				
- Basic and diluted		(50.92)	(5.39)	(0.85)
Non-IFRS loss per share for loss attributable to owners of the Company				
- Basic and diluted	(2.24)	(0.72)	(0.96)	(0.15)
Non-IFRS loss per ADS (5 ordinary shares equal to 1 ADS) for loss attributable to owners of the Company				
- Basic and diluted		(3.58)	(4.80)	(0.75)

(1) See the table above regarding the reconciliation of non-IFRS net loss to net loss for the year for more information of these non-IFRS adjustments.

Taxation

Cayman Islands

We are incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, we are not subject to income, corporation or capital gains tax in the Cayman Islands. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands.

Hong Kong

Our subsidiary incorporated in Hong Kong was subject to Hong Kong profits tax at a rate of 16.5% for taxable income earned in Hong Kong before April 1, 2018. Starting from the financial year commencing on April 1, 2018, the two-tiered profits tax regime took effect, under which the tax rate is 8.25% for assessable profits on the first HK\$2 million and 16.5% for any assessable profits in excess of HK\$2 million.

PRC

Our subsidiaries and consolidated VIEs in China are companies incorporated under PRC law and, as such, are subject to PRC enterprise income tax on their taxable income in accordance with the relevant PRC income tax laws. Pursuant to the PRC EIT Law, which became effective on January 1, 2008 and amended on December 29, 2018, a uniform 25% enterprise income tax rate is generally applicable to both foreign-invested enterprises and domestic enterprises, except where a special preferential rate applies. Certain entities in PRC have been eligible as High/New Technology Enterprises (“HNTEs”) with preferential tax rate of 15% as set out in PRC EIT Law. The enterprise income tax is calculated based on the entity’s global income as determined under PRC tax laws and accounting standards.

We were subject to VAT at a rate of 3%, 6% or 16% on the services we provided and related surcharges before April 1, 2019 and are subject to VAT at a rate of 3%, 6% or 13% on the services we provide and related surcharges after April 1, 2019. We are also subject to surcharges on VAT payments in accordance with PRC law.

As a Cayman Islands holding company, we may receive dividends from our PRC Subsidiaries through Genetron Health (Hong Kong) Company Limited. The PRC EIT Law and its implementing rules provide that dividends paid by a PRC entity to a nonresident enterprise for income tax purposes is subject to PRC withholding tax at a rate of 10%, subject to reduction by an applicable tax treaty with China. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, 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% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, a Hong Kong resident enterprise must meet the following conditions, among others, in order to apply the reduced withholding tax rate: (i) it must be a company; (ii) it must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (iii) it must have directly owned such required percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. In October 2019, the State Administration of Taxation promulgated the Administrative Measures for Nonresident Taxpayers to Enjoy Treatment under Tax Treaties, or SAT Circular 35 which became effective in January 2020. SAT Circular 35 provides that non-resident enterprises are not required to obtain pre-approval from the relevant tax authority in order to enjoy the reduced withholding tax. Instead, nonresident enterprises and their withholding agents may, by self-assessment and on confirmation that the prescribed criteria to enjoy the tax treaty benefits are met, directly apply the reduced withholding tax rate, and file necessary forms and supporting documents when performing tax filings, which will be subject to post-tax filing examinations by the relevant tax authorities. Accordingly, Genetron Health (Hong Kong) Company Limited may be able to benefit from the 5% withholding tax rate for the dividends it receives from our PRC Subsidiaries, if it satisfies the conditions prescribed under SAT Circular 81 and other relevant tax rules and regulations. However, according to SAT Circular 81 and SAT Circular 35, if the relevant tax authorities consider the transactions or arrangements, we have are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable withholding tax in the future.

If our holding company in the Cayman Islands or any of our subsidiaries outside of China were deemed to be a “resident enterprise” under the PRC EIT Law, it would be subject to enterprise income tax on its worldwide income at a rate of 25%. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Doing Business in the PRC—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 or ADS holders.”

5.B. Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flow from our operations. We expect to incur additional operating losses in the near future and our operating expenses will increase as we continue to expand our sales organization, increase our marketing efforts to drive market adoption, invest in clinical trials and develop new IVD products. We anticipate that our capital expenditure requirements will also increase in order to build additional capacity. Moreover, we expect to incur additional costs associated with operating as a public company, including expenses related to legal, accounting, regulatory, maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations.

Our principal source of liquidity has been revenue generated from sales of our services and products, proceeds from our equity financing, including our IPO on the Nasdaq in June 2020, and bank loans. As of December 31, 2021, we had RMB639.0 million (US\$100.3 million) in cash and cash equivalents, a significant portion of which were held by our PRC Subsidiaries and VIEs and their subsidiaries in China. Our cash and cash equivalents consist primarily of bank deposits and are primarily denominated in RMB and USD as of December 31, 2021. Based on our current business plan, we believe the proceeds from our financing activities and our current cash and cash equivalents will be sufficient to meet our anticipated cash needs, including our cash needs for working capital and capital expenditures, for at least the next 12 months.

We have based these future funding requirements on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We may, therefore, require additional cash due to changing business conditions or other future developments. If our available cash balances, anticipated cash generated from diagnosis and monitoring and development services, and the proceeds from our financing activities, including net proceeds from our initial public offering, are insufficient to satisfy our liquidity requirements, we may seek to sell additional common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to our Financial Prospects and Need for Additional Capital—We may need to obtain substantial additional financing to fund our growth and operations.” The sale of equity and convertible debt securities may result in dilution to our shareholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our ordinary shares. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. Additional capital may not be available on reasonable terms, or at all.

As a holding company with no material operations of our own, we conduct our operations primarily through our PRC Subsidiaries, variable interest entities and their subsidiaries. We are permitted under PRC laws and regulations to provide funding to our PRC Subsidiaries in China through capital contributions or loans, subject to the approval of government authorities and limits on the amount of capital contributions and loans. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Doing Business in the PRC—PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of our initial public offering 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.”

Substantially all of our future revenues are likely to continue to be denominated in RMB. Under existing PRC foreign exchange regulations, RMB may be converted into foreign currencies for current account items, including profit distributions, interest payments and trade- and service-related foreign exchange transactions, without prior SAFE approval as long as certain routine procedural requirements are fulfilled. Therefore, our PRC Subsidiaries are allowed to pay dividends in foreign currencies to us without prior SAFE approval by following certain routine procedural requirements. However, approval from or registration with competent government authorities is required where the 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. The PRC government may at its discretion restrict access to foreign currencies for current account transactions in the future.

The following table presents our selected consolidated cash flow data for the years ended December 31, 2019, 2020 and 2021.

	For the Year Ended December 31,			
	2019	2020	2021	
	RMB	RMB	RMB	US\$
	(in thousands)			
Net cash used in operating activities	(196,957)	(300,897)	(524,144)	(82,250)
Net cash used in investing activities	(96,807)	(84,649)	(136,275)	(21,384)
Net cash generated from/(used in) financing activities	371,731	1,744,512	(58,405)	(9,165)
Net increase/(decrease) in cash and cash equivalents	77,967	1,358,966	(718,824)	(112,799)
Cash and cash equivalents at beginning of year	62,126	139,954	1,375,766	215,887
Exchange differences on cash and cash equivalents	(139)	(123,154)	(17,900)	(2,808)
Cash and cash equivalents at end of year	139,954	1,375,766	639,042	100,280

Operating activities

Net cash used in operating activities was RMB524.1 million (US\$82.3 million) in 2021. The difference between our loss before income tax of RMB502.6 million (US\$78.9 million) and the net cash used in operating activities was mainly due to (i) share-based compensation of RMB54.1 million (US\$8.5 million), (ii) depreciation and amortization of RMB63.1 million (US\$9.9 million), and (iii) loss allowance for trade and other receivables and contract assets of RMB37.0 million (US\$5.8 million), partially offset by (i) finance net income of RMB14.1 million (US\$2.2 million), (ii) an increase in other receivables and prepayments of RMB44.4 million (US\$7.0 million) and (iii) an increase in trade receivables of RMB153.5 million (US\$24.1 million).

Net cash used in operating activities was RMB300.9 million in 2020. The difference between our loss before income tax of RMB3,069.0 million and the net cash used in operating activities was mainly due to (i) losses related to financial instruments with preferred rights of RMB2,823.4 million, (ii) share-based compensation of RMB30.0 million, (iii) depreciation and amortization of RMB53.2 million, and (iv) an increase in other payables and accruals of RMB11.9 million, partially offset by (i) finance net income of RMB22.3 million, (ii) an increase in trade receivables of RMB95.7 million and (iii) an increase in other receivables and prepayments of RMB22.9 million.

Net cash used in operating activities was RMB197.0 million in 2019. The difference between our loss before income tax of RMB676.0 million and the net cash used in operating activities was mainly due to (i) losses related to financial instruments with preferred rights of RMB359.9 million, (ii) share-based compensation of RMB35.9 million, (iii) depreciation and amortization of RMB46.6 million, (iv) an increase in other payables and accruals RMB41.6 million, and (v) an increase in trade payables of RMB26.6 million, in line with the growth of our business, partially offset by an increase in trade receivables of RMB48.2 million.

Investing activities

Net cash used in investing activities was RMB136.3 million (US\$21.4 million) in 2021, which was primarily attributable to (i) purchase of wealth management products of RMB1,650.4 million (US\$259.0 million), and (ii) purchase of derivative financial instruments of RMB415.3 million (US\$65.2 million), partially offset by redemption of wealth management products of RMB1,623.5 million (US\$254.8 million) and redemption of derivative financial instruments of RMB424.3 million (US\$66.6 million).

Net cash used in investing activities was RMB84.6 million in 2020, which was primarily attributable to purchase of wealth management products of RMB1,628.6 million, and purchase of property, plant and equipment, and intangible assets of RMB50.0 million, partially offset by redemption of wealth management products of RMB1,620.9 million.

Net cash used in investing activities was RMB96.8 million in 2019, which was primarily attributable to purchase of wealth management products of RMB479.1 million, partially offset by redemption of wealth management products of RMB395.7 million.

Financing activities

Net cash used in financing activities was RMB58.4 million (US\$9.2 million) in 2021, which was mainly attributable to repayments of borrowings of RMB69.1 million (US\$10.8 million), partially offset by proceeds from borrowings of RMB25.2 million (US\$3.9 million).

Net cash generated from financing activities was RMB1,744.5 million in 2020, which was mainly attributable to the proceeds from issuance of ordinary shares of RMB1,676.8 million, the proceeds from issuance of financial instruments with preferred rights of RMB70.0 million, and the proceeds from borrowings of RMB61.2 million, partially offset by the repurchase of ordinary shares of RMB4.1 million, proceeds from an investor upon reorganization RMB299.1 million offset by the repayments to investor upon reorganization RMB314.4 million, the repayments of borrowings RMB20.7 million and the principal elements of lease payments of RMB19.6 million.

Net cash generated from financing activities was RMB371.7 million in 2019, which was mainly attributable to the proceeds from issuance of financial instruments with preferred rights of RMB456.6 million, and the proceeds from borrowings of RMB33.0 million, partially offset by the repurchase of ordinary shares of RMB54.5 million, the repurchase of financial instruments with preferred rights of RMB43.3 million, the repayments of borrowings RMB9.8 million and the principal elements of lease payments of RMB12.3 million.

Capital Expenditures

Our capital expenditures are incurred primarily in connection with purchases of equipment and intangible assets. Our capital expenditures were RMB25.6 million, RMB50.0 million and RMB85.9 million (US\$13.5 million) in 2019, 2020, 2021, respectively. We intend to fund our future capital expenditures with our existing cash balance, net proceeds from our initial public offering, bank and other borrowings, and future operating cash flows. We will continue to make capital expenditures to meet the expected growth of our business. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

Holding Company Structure

Genetron Holdings Limited is a holding company with no material operations of its own. We conduct our operations primarily through our subsidiaries, consolidated VIEs and their subsidiaries. As a result, our ability to pay dividends depends upon dividends paid by our subsidiaries. If our subsidiaries or any newly formed subsidiaries incur debt on their own behalf in the future, the instruments governing their debt may restrict their ability to pay dividends to us.

In addition, our subsidiaries in China are permitted to pay dividends to us only out of their retained earnings, if any, as determined in accordance with the Accounting Standards for Business Enterprise as promulgated by the Ministry of Finance of the PRC ("PRC GAAP"). In accordance with PRC company laws, our consolidated VIEs in China must make appropriations from their after-tax profit to non-distributable reserve funds including (i) statutory surplus fund and (ii) discretionary surplus fund. The appropriation to the statutory surplus fund must be at least 10% of the after-tax profits calculated in accordance with PRC GAAP. Appropriation is not required if the statutory surplus fund has reached 50% of the registered capital of our consolidated VIEs. Appropriation to discretionary surplus fund is made at the discretion of our consolidated VIEs. Pursuant to the law applicable to China's foreign investment enterprise, our subsidiaries that are foreign investment enterprise in the PRC have to make appropriation from their after-tax profit, as determined under PRC GAAP, to reserve funds including (i) general reserve fund, (ii) enterprise expansion fund and (iii) staff bonus and welfare fund. The appropriation to the general reserve fund must be at least 10% of the after-tax profits calculated in accordance with PRC GAAP. Appropriation is not required if the reserve fund has reached 50% of the registered capital of our subsidiary. Appropriation to the other two reserve funds are at our subsidiary's discretion.

As an offshore holding company, we are permitted under PRC laws and regulations to provide funding from the proceeds of our offshore fund raising activities to our PRC Subsidiaries only through loans or capital contributions, and to the VIEs only through loans, in each case subject to the satisfaction of the applicable government registration and approval requirements. See "Item 3. Key Information—3.D. Risk Factors—Risks Related to Doing Business in the PRC—PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of our initial public offering 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." As a result, there is uncertainty with respect to our ability to provide prompt financial support to our PRC Subsidiaries and VIEs when needed. Notwithstanding the foregoing, our PRC Subsidiaries may use their own retained earnings (rather than RMB converted from foreign currency denominated capital) to provide financial support to the VIEs either through entrustment loans from our PRC Subsidiaries to the VIEs or direct loans to such VIE's nominee shareholders, which would be contributed to the VIEs as capital injections. Such direct loans to the nominee shareholders would be eliminated in our consolidated financial statements against the VIE's share capital.

Off-Balance Sheet Commitments and Arrangements

We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties. We have not entered into any derivative contracts that are indexed to our shares and classified as shareholder's equity or that are not reflected in our consolidated financial statements. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity or market risk support to such entity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or product development services with us.

Contractual Obligations

	Payments Due by December 31, 2021				
	Total	Less than 1 year	1-3 years (RMB in thousands)	3-5 years	More than 5 years
Capital commitments ⁽¹⁾	34,772	34,772	—	—	—
Operating leases ⁽²⁾	62,003	24,082	29,403	6,836	1,682
Short-term bank borrowings ⁽³⁾	15,707	15,707	—	—	—
Long-term borrowing ⁽⁴⁾	4,499	4,499	—	—	—
Total	116,981	79,060	29,403	6,836	1,682

(1) Capital commitments relate to contracts for equipment and intangible assets.

(2) Operating leases relate to certain office buildings under non-cancellable operating lease agreements.

(3) The short-term bank borrowings were obtained for working capital purpose.

(4) The long-term borrowing was obtained for working capital purpose.

Other than those shown above, we did not have any significant capital and other commitments, long-term obligations or guarantees as of December 31, 2021.

5.C. Research and Development, Patents and Licenses, Etc.

Our advanced technology infrastructure and capabilities allow us to efficiently and effectively provide our services. See “Item 4. Information on the Company—4.B. Business Overview—Our Proprietary Technologies,” “Item 4. Information on the Company—4.B. Business Overview—Our Research and Development Capabilities,” and “Item 4. Information on the Company—4.B. Business Overview—Intellectual Property.”

As of the date of this annual report, our PRC subsidiaries and the VIEs had obtained the following material licenses and approvals, and they are currently valid and required for our operations in China.

License/Permit	Holder	Grant Date	Expiration Date
Medical Device Manufacturing Permit	Genetron Health (Beijing) Co., Ltd.	June 24, 2020	February 8, 2023
Medical Device Manufacturing Permit	Genetron Health (Chongqing) Co., Ltd.	July 21, 2020	December 27, 2022
Medical Device Operation Permit	Genetron Health (Beijing) Co., Ltd.	June 29, 2020	June 28, 2025
Medical Device Operation Permit	Genetron Health (Chongqing) Co., Ltd.	May 22, 2020	May 29, 2023
National High-tech Enterprise Certificate	Genetron Health (Beijing) Co., Ltd.	December 2, 2019	December 1, 2022
Medical Institution Practice License	Guangzhou Genetron Medical Laboratory Co., Ltd.	December 17, 2019	December 17, 2024
Medical Institution Practice License	Beijing Genetron Medical Laboratory Co., Ltd.	May 10, 2021	May 10, 2026
Medical Institution Practice License	Shanghai Genetron Medical Laboratory Co., Ltd.	May 26, 2021	July 21, 2026
Medical Institution Practice License	Chongqing Genetron Medical Laboratory Co., Ltd.	August 9, 2017	August 8, 2022
Medical Institution Practice License	Tianjin Genetron Clinic Co., Ltd.	August 4, 2021	April 11, 2026
Filing Receipt of Pathogenic Microbe Bio-Safety Lab (BSL-2)	Guangzhou Genetron Medical Laboratory Co., Ltd.	May 25, 2020	–
Record-Filing Notice of Pathogenic Microbe Lab and Activities Conducted Therein in Beijing	Beijing Genetron Medical Laboratory Co., Ltd.	May 9, 2020	–
Record-Filing Certificate of Pathogenic Microbe Lab in Shanghai (BSL-2)	Shanghai Genetron Medical Laboratory Co., Ltd.	May 19, 2021	–
Record-Filing Certificate of Bio-Safety Lab in Chongqing (BSL-2)	Chongqing Genetron Medical Laboratory Co., Ltd.	January 11, 2021	–
Acceptance Certificate of Technique Used by Clinical Gene Amplification Testing Lab	Guangzhou Genetron Medical Laboratory Co., Ltd.	February 1, 2021	January 31, 2026
Medical Device Registration Certificate (Human 8 Gene Mutation Comprehensive Detection Kit (Semiconductor Sequencing Method)) Registration No.: Guoxiezhuazhun 2020340072	Genetron Health (Beijing) Co., Ltd.	January 22, 2020	January 21, 2025
Medical Device Registration Certificate (Biochip Reader) Registration No.: Yuxiezhuazhun 20172400136	Genetron Health (Chongqing) Co., Ltd.	October 31, 2017	October 30, 2022
Medical Device Registration Certificate (Fully-automated Sampling System) Registration No.: Yuxiezhuazhun 20192220364	Genetron Health (Chongqing) Co., Ltd.	November 25, 2019	November 24, 2024
Medical Device Registration Certificate (Gene Sequencing Instrument) Registration No.: Guoxiezhuazhun 20193220820	Genetron Health (Chongqing) Co., Ltd.	November 1, 2019	October 31, 2024
Medical Device Registration Certificate (Gene Sequencing Instrument) Registration No.: Guoxiezhuazhun 2020032220081	Genetron Health (Chongqing) Co., Ltd.	January 22, 2020	January 21, 2025

For risks associated with these approvals, permits or registrations, please see “Item 3. Key Information—3.D. Risk Factor—Risks Related to Our Business and Industry—We may be adversely affected by the uncertainties and changes in the regulation of cancer genomic testing service industry or LDT industry in general in the PRC, and any lack of requisite approvals, permits, registrations or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects, and “Item 3. Key Information—3.D. Risk Factor—Risks Related to Our Business and Industry—If we fail to obtain applicable licenses or registrations for our IVD medical products, we will be unable to commercially manufacture, distribute and market our products, and our commercialization of IVD medical products might be substantially harmed.”

5.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, 2021 that are reasonably likely to have a material and 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 results of operations or financial condition.

5.E. Critical Accounting Estimates

We prepare our financial statements in accordance with the IFRS issued by the IASB, which requires us to make estimates, assumptions and judgements that affect the reported amounts of assets, liabilities at the balance sheet dates and revenues and expenses during the reporting periods. We continually evaluate these judgments and estimates based on our own historical experience, knowledge and assessment of current business and other conditions, our expectations regarding the future based on available information and assumptions that we believe to be reasonable, which together form our basis for making judgments about matters that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, our actual results could differ from those estimates. The critical accounting estimates should be read in conjunction with our risk factors as disclosed in “Item 3. Key Information—3.D. Risk Factors.” See Note 4 to our consolidated financial statements for the year ended December 31, 2021 for more information on our critical accounting policies.

Loss allowance of receivables

The allowance for credit losses represents our estimate of the expected lifetime credit losses inherent in receivables as of the balance sheet date. The adequacy of allowance for receivables is assessed quarterly, and the assumptions and models used in establishing the allowance are evaluated regularly. Because credit losses can vary substantially over time, estimating credit losses requires a number of assumptions. Changes in assumptions affect net loss allowance for financial and contract assets on our consolidated statements of loss and the allowance for credit losses contained within receivables, net on our consolidated balance sheets. One of the significant assumptions is macroeconomic forecasts involved in the model to estimate the loss allowance of receivables. The related macroeconomic factors used are country specific and include variables such as gross domestic product (GDP), producer price index (PPI) and consumer price index (CPI). Besides, there are other significant assumptions including incorporation of historical loss experience, assessment of risk characteristics by group, determination of remaining expected life, and the development and weighting of scenarios.

See Note 3.1 to our consolidated financial statements for the year ended December 31, 2021 for more information regarding loss allowance of trade receivables and contract assets.

Fair value of share-based compensation

Prior to our initial public offering on the Nasdaq in June 2020, we estimated the fair value of each award on the grant date using the binomial option pricing model with the assistance of an external independent professional valuer. The binomial model requires developing estimates of risk-free interest rate, expected volatility, vesting period, dividend yield based on actual and expected business performance, market analyses. Subsequent to our IPO, the fair value of the shares is calculated based on closing market price of our ADS on the NASDAQ Global Market on the date of grant, the number of awards that are expected to vest based on the service and non-market performance vesting conditions.

At the end of each period, we revise the estimation of the expected number of restricted shares and options that are expected to be vested based on the service and non-market performance vesting conditions, and in consideration of the estimated forfeiture rates based on historical employee turnover rates. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity. We apply prospective treatment in respect of accounting for modifications of equity-settled awards that reduce the vesting period, if any.

See Note 27 to our consolidated financial statements for the year ended December 31, 2021 for more information regarding the key assumptions for the awards granted.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

6.A. Directors and Senior Management

The following table sets forth information regarding our executive officers and directors as of the date of this annual report.

Name	Age	Position/Title
Executive Officers		
Sizhen Wang	45	Chief Executive Officer, Director and Chairman of the Board
Hai Yan, Ph.D./M.D.	54	Chief Scientific Officer and Director
Yuchen Jiao, Ph.D./M.D.	44	Chief Technology Officer
Evan Ce Xu	40	Chief Financial Officer
Yun-Fu Hu, Ph.D	60	Chief Medical Officer
Fengling Zhang	64	Vice President
Non-executive Directors		
Xia Wu	40	Director
Shan Fu	54	Director
Chao Tang, Ph.D	63	Director
Dian Kang	73	Independent Director
Webster Cavenee	70	Independent Director
Wing Kee Lau	57	Independent Director

Executive Officers

Sizhen Wang is our co-founder and has served as our Chief Executive Officer since May 2015. Mr. Wang has served as our Director since April 2018, and as our Chairman of the Board since 2021. Prior to founding our Company, Mr. Wang co-founded iTalkBB in 2004, a company providing voice, TV, data and mobile communication services globally and served as executive vice president until September 2013. He led iTalkBB to enter America's VoIP residential service market and expand its business to Canada, Australia, Singapore and China over eight years and made iTalkBB to become the biggest VoIP and IPTV service provider for overseas Chinese. He previously spent seven years in finance industry, where he gained valuable experience working for Capital One and GD Capital. Mr. Wang received his bachelor's degree in economics from the Central University of Finance and Economics in 1995 and his M.B.A. degree from the HEC Paris School of Management in 2000.

Hai Yan, Ph.D./M.D. is the Co-Founder and Chief Scientific Officer of Genetron Health. Dr. Yan received his medical degree from Peking University Health Center, Ph.D. degree in Molecular and Cellular Biology Program from Columbia University, and post-doctoral training at The Johns Hopkins University School of Medicine. Dr. Yan was a faculty member at Duke University School of Medicine. He was the Henry S. Friedman Distinguished Professor of Neuro-Oncology, and a Professor of Pathology. He once served as the Director of Neuro Oncology Program at Duke Cancer Institute. He is an elected member of the American Society for Clinical Investigation (ASCI). He was honored as a Damon Runyon Foundation Scholar, an American Cancer Society Scholar, a V Foundation Scholar, and a James S. McDonnell Scholar. He received the 2014 AACR Team Science Award. In 2021, he was awarded the International Prize for Translational Neuroscience from the Gertrud Reemtsma Foundation through the Max Planck Society in Germany. Dr. Yan received his M.D. in basic medicine from Peking University Health Center in 1991 and his Ph.D. degree in molecular and cellular biology from Columbia University in 1997. Dr. Yan also served as research associate at Johns Hopkins University.

Yuchen Jiao, Ph.D./M.D. has served as our Chief Technology Officer since August 2017. From December 2013 to date, Dr. Jiao is also serving as a professor at National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences, focusing on the studying of cancer genomics and early diagnosis of cancer. Dr. Jiao's research has been published in multiple renowned academic journals such as *Science* and *Nature Genetics*. Dr. Jiao has also received various awards throughout his academic and research careers, including Hans Joaquim Prochaska Research Award, which was awarded by the Johns Hopkins School of Medicine. Dr. Jiao received his M.D. in clinical medicine from Peking Union Medical College in July 2003, and his Ph.D. degree in biological chemistry at the Johns Hopkins University in 2009.

Evan Ce Xu has served as our Chief Financial Officer since March 2018. Mr. Xu has more than 12 years of experience in corporate finance and mergers and acquisition transactions. Prior to joining our Company, Mr. Xu served as director of investment banking division at Deutsche Bank AG, Hong Kong Branch, from December 2016 to March 2018. Prior to that, Mr. Xu served as associate and executive director at investment banking division of Goldman Sachs (Asia) L.L.C., from July 2010 to September 2016. Prior to that, Mr. Xu spent a number of years in various roles at different financial institutions, such as Citigroup, Lehman Brothers and Nomura Securities (Hong Kong) Limited. Mr. Xu received his bachelor's degree in computer engineering from the National University of Singapore in 2004 and his master's degree in information and computer engineering from the National University of Singapore in 2005.

Yun-Fu Hu, Ph.D. has served as our Chief Medical Officer since 2020. Dr. Hu brings over two decades of experience in regulatory and managerial capacities related to medical devices and pharmaceutical industries. Dr. Hu had more than ten years of service at US Food and Drug Administration ("FDA"), where he had served as Deputy Director and other positions at Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health, Center for Device and Radiological Health. During his tenure at FDA, Dr. Hu supervised a staff of scientists, engineers, consumer safety officers and medical officers in premarket reviews and post-market compliance of IVD products and LDTs for genetic testing, molecular cancer diagnostics, companion diagnostics, radio dosimetry, digital pathology and artificial intelligence devices. Some of the notable authorizations by Dr. Hu's group at FDA include: the first NGS-based LDT as CDx (Foundation Medicine FoundationFocus CDxBRCA); the first NGS-based CDx kit (Thermo Fisher OncoPrint Dx Target Test); the first NGS-based LDT for tumor profiling (MSK-IMPACT) and later on FoundationOne CDx); the first liquid biopsy test for NSCLC (Roche Cobas EGFR Mutation Test v2); and FDA's only two approved cancer screening tests in the last decade (Exact Sciences' Cologuard and Epigenomics' Epi ProColon). He was a member of the steering committee to stand up the FDA's Oncology Center of Excellence (OCE) under the 21st Century Cures and served as the Center's first Acting Associate Director of In Vitro Diagnostics.

Prior to joining FDA, Dr. Hu has more than ten years of product development experience in diagnostic and pharmaceutical industries, including his prior employments at GlaxoSmithKline and Becton Dickinson Diagnostic Systems. Dr. Hu received his bachelor degree from Central China Agricultural University in 1983, his master degree in reproductive endocrinology from the Ohio State University in 1990 and his Ph.D. degree in veterinary physiology & pharmacology from the Ohio State University in 1994 followed by a postdoctoral cancer research fellowship at Fox Chase Cancer Center. Dr. Hu has four US patents and over 30 publications.

Fengling Zhang has served as our Vice President since June 2021. Ms. Zhang is primarily responsible for the management of market access and administrative affairs. Ms. Zhang has been serving as the vice president of Genetron Health since February 2017. She currently also serves as the supervisor of Guangzhou Genetron Bio-Technology Co., Ltd. and Guangzhou Genetron Medical Laboratory Co., Ltd.

Prior to joining us, Ms. Zhang served as a secretary and the overall quality management coordinator at China Hewlett-Packard Co., Ltd. from August 1985 to December 1988. She then served as the office manager at Ericsson Communications Co., Ltd. Beijing Representative Office from December 1988 to August 1992. Subsequently, she worked as the sales manager at New Power Group Beijing Representative Office from August 1992 to March 1994. After that, she worked as the contract manager at SRT Communications Inc. Beijing Office from March 1994 to October 1998. Ms. Zhang then joined Shanghai Bell Alcatel Co., Ltd. in October 1998 and served as the sales director, director of government affairs and the vice president from October 1998 to March 2013. Ms. Zhang received her M.B.A. degree from Fudan University and Hong Kong University Joint Program in 2006.

Non-executive Directors

Xia Wu has served as our Director since September 2017. Ms. Wu has over 10 years of experience in investments, particularly healthcare industry. Ms. Wu has been serving in CICC Jia Cheng Investment Management Company Limited since July 2008 and has served as vice president from January 2012 to December 2014, as executive director from January 2015 to February 2019, and as managing director since March 2019. She currently serves as a member of the investment committee of CICC Kangrui I (Ningbo) Equity Investment Limited Partners (Limited Partnership) and CICC Kangrui Phase II (Chengdu) Healthcare Venture Capital Partnership (Limited Partnership). Ms. Wu received her bachelor degree in finance from Peking University in 2003 and her master degree in economics and finance from the Warwick Business School of Warwick University in 2005.

Shan Fu has served as our director since June 2021. Prior to joining our Company, Mr. Fu served as joint chief executive officer and the greater China chief executive officer of Vivo Capital LLC since October 2013, prior to which he served as the chief representative of China at Blackstone Group from June 2008 to October 2013. Mr. Fu served as a non-executive director of Sinovac Biotech Ltd., (a company listed on the Nasdaq, symbol: SVA) since July 2018, of TOT BIOPHARM International Company Limited (a company listed on the Stock Exchange, stock code: 1875) since November 2019, and of InnoCare Pharma Limited (a company listed on the Stock Exchange, stock code: 9969) since March 2020. Mr. Fu obtained his bachelor's degree in history from Peking University in Beijing, the PRC in July 1988 and his master's degree in history from Peking University in July 1991.

Chao Tang has served as our director since June 2021. Dr. Tang served as a chair professor of physics and systems biology and the executive dean of the Academy for Advanced Interdisciplinary Studies at Peking University since October 2011. In his early career, Dr. Tang worked on pioneering research in the fields of statistical physics, condensed matter physics, dynamical and complex systems while in the United States. His current research interest is at the interface between physics and biology, in particular systems biology and biological physics. Dr. Tang was a tenured full professor at the University of California San Francisco from March 2005 to September 2011. Dr. Tang was elected fellow of the American Physical Society in November 1997, and an academician of the Chinese Academy of Sciences in August 2019. He served as the director of the Center for Quantitative Biology at Peking University (formerly known as Center for Theoretical Biology) since September 2001. Dr. Tang served as the co-editor-in-chief of the journal Quantitative Biology from since 2012. Dr. Tang also served as a postdoctoral researcher at the Brookhaven National Laboratory from September 1986 to August 1988, and at the Kavli Institute for Theoretical Physics of the University of California, Santa Barbara from September 1988 to October 1991. Dr. Tang held research positions at NEC Research Institute from October 1991 to March 2005. Dr. Tang obtained his bachelor's degree in mechanics from the University of Science and Technology of China in Hefei, Anhui Province, the PRC in August 1981, and obtained his Ph.D. degree in physics from the University of Chicago in Chicago, the United States in June 1986.

Dian Kang has served as our independent director since June 2020. Mr. Kang served as the chief executive officer, and the executive director and the chairman of board of directors of New China Life Insurance Company Ltd. (HKEx: 1336) from 2013 to 2016 and from 2009 to 2016, respectively. Prior to that, he served as chairman of the board of supervisors of Shenzhen Development Bank Company Limited (a company listed on the Shenzhen Stock Exchange, stock code: 000001) from 2005 to 2009, chairman of Springridge Investment Management Limited from 2001 to 2005, director and vice president of the Guangdong Enterprises (Holdings) Limited, chairman of the board of the Guangdong Securities Limited and Guangdong Capital Holdings Ltd. from 1994 to 2000, as well as vice president of China National Packaging Corporation from 1990 to 1994. He also served as vice president of China Agribusiness Trust & Investment Corporation from 1987 to 1990 and worked at the Overseas Investment Department of China International Trust & Investment Corporation from 1984 to 1987. Mr. Kang also served as an independent non-executive director of Silver Grant International Industries Limited (a company listed on the HKSE, stock code: 00171) from May 1998 to February 2014. Mr. Kang graduated from Beijing Steel and Iron Institute in 1982. He also received a master's degree in economics from the Graduate School of the Chinese Academy of Social Sciences in 1984.

Webster Cavenee, Ph.D. has served as our independent director since June 2020. He has served as a director of Strategic Alliances in Central Nervous System Cancers at Ludwig Cancer Research since 2015 and as Distinguished Professor at the University of California San Diego since 1991. Dr. Cavenee joined Ludwig Cancer Research as a member in 1985 and served as Ludwig Montreal branch director from December 1985 to September 1991. Dr. Cavenee served as Ludwig San Diego branch director from September 1991 to June 2015. Prior to joining Ludwig Cancer Research, Dr. Cavenee did postdoctoral work between November 1977 and September 1983 at the Jackson Laboratory, at Massachusetts Institute of Technology, to and the Howard Hughes Medical Institute at the University of Utah. Dr. Cavenee held professorships at the University of Cincinnati from September 1983 to December 1985 and at McGill University from December 1985 to September 1991. Dr. Cavenee received his Bachelor of Science degree in Microbiology from Kansas State University in 1973 and his Ph.D. with honors from the University of Kansas in 1977.

Wing Kee Lau has served as our independent director since June 2020. Mr. Lau served as the director of Perfect World Holding Company Limited during the period from April 2016 to June 2018. Mr. Lau served as the Chief Financial Officer of Perfect World Company Limited (Nasdaq: PWRD) from March 2007 to March 2016. Prior to joining PWRD, Mr. Lau was the chief financial officer and company secretary of Beijing Media Corporation Limited (HKEX: 1000) from November 2004 to February 2007. From July 2000 to October 2004, Mr. Lau was the group finance director of Shanghai Ogilvy & Mather Advertising Limited Beijing Branch. Mr. Lau worked for PricewaterhouseCoopers Hong Kong, Shanghai and Beijing offices from September 1990 to June 2000. Mr. Lau received his bachelor's degree in business administration from Hong Kong Baptist University in 1990 and his EMBA degree from Cheung Kong Graduate School of Business in 2011. He is a member of Association of Chartered Certified Public Accountants and Hong Kong Institution of Certified Public Accountants.

6.B. Compensation

Compensation

For the fiscal year ended December 31, 2021, we paid an aggregate of RMB8.8 million (US\$1.4 million) in cash to our then incumbent executive officers, and we did not pay any cash compensation to our non-executive directors. We have accrued RMB1.6 million (US\$0.2 million) for compensation to our independent non-executive directors. We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors. Our PRC Subsidiaries, variable interest entities and their subsidiaries are required by law to make contributions equal to certain percentages of each employee's salary for his or her pension insurance, medical insurance, unemployment insurance and other statutory benefits and a housing provident fund. For share incentive grants to our directors and executive officers, see "—Share Incentive Plan."

Employment Agreements and Indemnification Agreements

We have entered into employment agreements with each of our executive officers. Each of our executive officers is employed for a specified time period, which can be renewed upon both parties' agreement before the end of the current employment term. We may terminate an executive officer's employment for cause at any time without advance notice in certain events. We may terminate an executive officer's employment by giving a prior written notice or by paying certain compensation. An executive officer may terminate his or her employment at any time by giving a prior written notice.

Each executive officer has agreed to hold, unless expressly consented to by us, at all times during and after the termination of his or her employment agreement, in strict confidence and not to use, any of our confidential information or the confidential information of our customers and suppliers. In addition, each executive officer has agreed to be bound by certain non-competition and non-solicitation restrictions during the term of his or her employment and for two years following the last date of employment.

We have also entered into indemnification agreements with each of our directors and executive officers. Under these agreements, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our Company.

Share Incentive Plan

2017 Genetron Health Share Incentive Plan and 2018 Genetron Health Share Incentive Plan

In January 2017, Genetron Health adopted the 2017 Genetron Health Share Incentive Plan, or the 2017 Plan. Under the 2017 Plan, Genetron Health reserved 2,375,800 options to certain of its management members and employees to purchase the equity interests of Genetron Health. The term of the options will not exceed ten years from the date of the grant.

In June 2018, Genetron Health adopted the 2018 Genetron Health Share Incentive Plan, or the 2018 Plan. Under the 2018 Plan, Genetron Health reserved 4,416,500 options to certain of its management members and employees to purchase the equity interests of Genetron Health. The term of the options will not exceed ten years from the date of the grant.

The options granted under the 2017 Plan and 2018 Plan have been completely replaced by the awards under the 2019 Plan.

2019 Genetron Health Share Incentive Plan and 2019 Genetron Health Share Incentive Scheme

We adopted the 2019 Genetron Health Share Incentive Plan, or the 2019 Plan, in July 2019, and the 2019 Genetron Health Share Incentive Scheme, or the 2019 Scheme, in November 2019. The purpose of the 2019 Plan and the 2019 Scheme is to attract and retain exceptionally qualified personnel and to encourage them to acquire a proprietary interest in our growth and performance. The 2019 Plan provides for the issuance of up to an aggregate of 33,961,500 of our ordinary shares. As of March 31, 2022, we have granted 87 awards under the 2019 Plan to purchase up to 12,151,960 ordinary shares, excluding awards that were forfeited, cancelled or exercised after the relevant grant dates. The 2019 Scheme provides for the issuance of up to an aggregate of 20,830,100 of our ordinary shares. As of March 31, 2022, we have granted 223 awards under the 2019 Scheme to purchase up to 5,331,575 ordinary shares.

We initially issued 9,523,900 and 13,031,720 ordinary shares to Genetron Health (Hong Kong) Limited and EVER PRECISE INVESTMENTS LIMITED, respectively, our employee shareholding platforms established to hold the ordinary shares underlying the restricted shares and options granted under the 2019 Plan and the 2019 Scheme. As of March 31, 2022, some of the awards had been exercised and as a result Genetron Health (Hong Kong) Limited and EVER PRECISE INVESTMENTS LIMITED directly held 4,272,000 and 7,132,435 ordinary shares, respectively, as of March 31, 2022. In addition, we deposited 9,950,000 ordinary shares in the form of ADSs to facilitate exercise of awards under the 2019 Plan and the 2019 Scheme as of March 31, 2022. Accordingly, a total of 21,340,740 and 21,304,435 ordinary shares were issued but deemed not outstanding and were excluded from the number of our total outstanding ordinary shares as of December 31, 2021 and March 31, 2022, respectively.

The terms under the 2019 Plan and the 2019 Scheme are substantially the same. The following paragraphs summarize the principal terms of the 2019 Plan and the 2019 Scheme.

Types of Awards. The 2019 Plan and the 2019 Scheme permit the awards of options, phantom options, restricted shares, restricted share units (“RSUs”) and phantom RSUs under the 2019 Plan and the 2019 Scheme.

Plan Administration. The 2019 Plan and the 2019 Scheme shall be administered by our Board or the management committee of the Company to be established by the Board unless otherwise resolved by the Board.

Eligibility. The plan administrators may decide that an award under the 2019 Plan and the 2019 Scheme be granted to any employee or director of the Company or its related entities, or that it be granted to any consultant, adviser or other person who provides services to the Company or its related entities, selected by the Plan Administrators.

Award Agreements. Each award under the 2019 Plan and the 2019 Scheme shall be evidenced and governed exclusively by an award agreement executed by the Company and the participants, including any amendments thereto. The terms of the award agreements will be determined by the plan administrators and consistent with the terms of the 2019 Plan and the 2019 Scheme.

Conditions of Award. The plan administrators shall determine the participants, types of awards, numbers of shares to be covered by awards, terms and conditions of each award, including, but not limited to, the types of awards, award vesting schedule, number of awards to be granted and the number of shares to be covered by the awards, exercise price of options (if applicable), restricted shares price (if applicable), any restrictions or limitations on the award and term of each award.

Transfer Restrictions. No right of interest of a participant in any award may be pledged, encumbered, or hypothecated to or in favor of any party other than the Company or its related entities, or shall be subject to any lien, obligation, or liability of such participant to any other party other than the Company or its related entities. This restriction does not apply to the transmission of an award on the death of a participant to his or her personal representatives, nor does it apply to the assignment of an award, with the prior written consent of the plan administrators, subject to any terms and conditions the plan administrators impose.

Reduction or Clawback of Awards. Within the time period specified in the 2019 Plan and the 2019 Scheme, the plan administrators may decide that the number of shares subject to any award be reduced, that the participant must transfer to or to the order of the Company a number of shares equal or less than the number of shares issued or transferred to such participant pursuant to the award, or that the award be otherwise limited or paid back to the Company, if certain events occur. Such events include but are not limited to, that the participant has engaged in financial misstatement, that the participant breaches any non-competition covenant, and that the participant's behavior has resulted in material reputational damage to the Company or its related entities as determined by the plan administrators.

Amendment of the 2019 Plan and the 2019 Scheme. The plan administrators may in its sole discretion at any time amend the 2019 Plan and the 2019 Scheme in any way, including any performance condition or other terms of an award granted.

Termination of the 2019 Plan and the 2019 Scheme. The 2019 Plan and the 2019 Scheme will terminate on the tenth anniversary of our listing on Nasdaq or any earlier date as the plan administrators may determine. No additional awards may be granted after termination.

The following table summarizes, as of March 31, 2022, the number of ordinary shares under outstanding options, restricted shares and RSUs that we granted to our directors and executive officers under the 2019 Plan, which replaced the 2017 Plan and the 2018 Plan, and under the 2019 Scheme.

Name	Ordinary Shares Underlying Equity Awards Granted	Exercise Price (US\$per Share)	Date of Grant	Date of Expiration
Executive Officers:				
Sizhen Wang	—	—	—	—
Hai Yan, Ph.D./M.D.	—	—	—	—
Yuchen Jiao, Ph.D./M.D.	2,809,000	0.03	October 14, 2019	October 14, 2029
Evan Ce Xu	*	*	March 31, 2018	March 31, 2028
Yun-Fu Hu	*	*	October 1, 2020	October 1, 2030
Fengling Zhang	*	*	June 15, 2018 and October 1, 2019	June 15, 2028 and October 1, 2029
Non-Executive Directors:				
Xia Wu	—	—	—	—
Shan Fu	—	—	—	—
Chao Tang	—	—	—	—
Dian Kang	*	*	July 1, 2020	July 1, 2030
Webster Cavenee	*	*	July 1, 2018 and July 1, 2020	July 1, 2028 and July 1, 2030
Wing Kee Lau	*	*	July 1, 2020	July 1, 2030
All directors and executive officers as a group	7,368,000	0.03 – 0.99	Various dates from March 31, 2018 to October 1, 2020	Various dates from March 31, 2028 to October 1, 2030

* Less than 1% of our total outstanding shares.

As of March 31, 2022, our award holders other than our directors and executive officers as a group held awards to purchase 10,115,535 ordinary shares, with a weighted-average exercise price of US\$0.30 per share under the 2019 Plan and the 2019 Scheme.

6.C. Board Practices

Board of Directors

Our Board consists of eight directors, including three independent directors, namely Dian Kang, Webster Cavenee and Wing Kee Lau. A director is not required to hold any shares in our Company to qualify to serve as a director. The Corporate Governance Rules of the Nasdaq generally require that a majority of an issuer's board of directors must consist of independent directors. However, the Corporate Governance Rules of the Nasdaq permit foreign private issuers like us to follow "home country practice" in certain corporate governance matters. We rely on this "home country practice" exception and do not have a majority of independent directors serving on our Board.

A director who is in any way, whether directly or indirectly, interested in a contract or proposed contract with our Company is required to declare the nature of his or her interest at a meeting of our directors. A general notice given to the directors by any director to the effect that he or she is a member, shareholder, director, partner, officer or employee of any specified company or firm and is to be regarded as interested in any contract or transaction with that company or firm shall be deemed a sufficient declaration of interest for the purposes of voting on a resolution in respect to a contract or transaction in which he/she has an interest, and after such general notice it shall not be necessary to give special notice relating to any particular transaction. A director may vote in respect of any contract or proposed contract or arrangement notwithstanding that he/she may be interested therein and if he/she does so, his/her vote shall be counted and he/she may be counted in the quorum at any meeting of the directors at which any such contract or proposed contract or arrangement is considered, subject to any separate requirement for Audit Committee approval under applicable law or the Listing Rules of the Nasdaq. Our Board may exercise all of the powers of our Company to borrow money, to mortgage or charge its undertaking, property and uncalled capital, or any part thereof, and to issue debentures, debenture stock or other securities whenever money is borrowed or as security for any debt, liability or obligation of our Company or of any third party. None of our directors has a service contract with us that provides for benefits upon termination of service as a director.

Committees of the Board of Directors

We have established an audit committee, a compensation committee and a nominating and corporate governance committee under our Board. We have also adopted a charter for each of the three committees. Each committee's members and functions are described below.

Audit Committee. Our audit committee consists of Dian Kang, Webster Cavenee and Wing Kee Lau, and is chaired by Wing Kee Lau. We have determined that each of Dian Kang, Webster Cavenee and Wing Kee Lau satisfies the requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq and meet the independence standards under Rule 10A-3 under the Exchange Act. We have determined that Wing Kee Lau qualifies as an "audit committee financial expert." The audit committee oversees 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:

- reviewing and recommending to our Board for approval, the appointment, re-appointment or removal of the independent auditor, after considering its annual performance evaluation of the independent auditor;
- approving the remuneration and terms of engagement of the independent auditor and pre-approving all auditing and non-auditing services permitted to be performed by our independent auditors at least annually;
- obtaining a written report from our independent auditor describing matters relating to quality control procedures;
- reviewing with the independent registered public accounting firm any audit problems or difficulties and management's response;
- discussing with our independent auditor, among other things, the audits of the financial statements, including whether any material information should be disclosed, issues regarding accounting and auditing principles and practices;
- 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 the adequacy and effectiveness of our accounting and internal control policies and procedures and any special steps taken to monitor and control major financial risk exposures;
- at least annually, reviewing and reassessing the adequacy of the committee charter;
- approving annual audit plans, and undertaking an annual performance evaluation of the internal audit function;

- establishing and overseeing procedures for the handling of complaints and whistleblowing;
- meeting separately and periodically with management and the independent registered public accounting firm;
- overseeing compliance with our code of business conduct and ethics; and
- reporting periodically to the Board.

Compensation Committee. Our compensation committee consists of Sizhen Wang, Xia Wu and Dian Kang and is chaired by Sizhen Wang. We have determined that Dian Kang satisfies the “independence” requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq. The compensation committee assists the Board 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 their compensation is deliberated upon. The compensation committee is responsible for, among other things:

- overseeing the development and implementation of compensation programs in consultation with our management;
- at least annually, reviewing and approving, or recommending to the Board for its approval, the compensation for our executive officers;
- at least annually, reviewing and recommending to the Board for determination with respect to the compensation of our non-executive directors;
- at least annually, reviewing periodically and approving any incentive compensation or equity plans, programs or other similar arrangements;
- reviewing executive officer and director indemnification and insurance matters;
- overseeing our regulatory compliance with respect to compensation matters, including our policies on restrictions on compensation plans and loans to directors and executive officers;
- periodically reviewing and reassessing the adequacy of the committee charter;
- selecting compensation consultant, legal counsel or other adviser only after taking into consideration all factors relevant to that person's independence from management; and
- reporting regularly to the Board.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee consists of Sizhen Wang, Dian Kang and Webster Cavenue, and is chaired by Sizhen Wang. We have determined that each of Dian Kang and Webster Cavenue satisfies the “independence” requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq. The nominating and corporate governance committee assists the Board in selecting individuals qualified to become our directors and in determining the composition of the Board and its committees. The nominating and corporate governance committee is responsible for, among other things:

- recommending nominees to the Board for election or re-election to the Board, or for appointment to fill any vacancy on the Board;
- reviewing annually with the Board the current composition of the Board with regards to characteristics such as independence, knowledge, skills, experience, expertise, diversity and availability of service to us;
- developing and recommending to our Board such policies and procedures with respect to nomination or appointment of members of our Board and chairs and members of its committees or other corporate governance matters as may be required pursuant to any SEC or Nasdaq rules, or otherwise considered desirable and appropriate;

- selecting and recommending to the Board the names of directors to serve as members of the audit committee and the compensation committee, as well as of the nominating and corporate governance committee itself;
- periodically reviewing and reassessing the adequacy of the committee charter; and
- evaluating the performance and effectiveness of the Board as a whole.

Duties and Functions 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 what 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 exercise the skill they actually possess and such care and diligence that a reasonable prudent person would exercise in comparable circumstances. 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. Our Company has 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. The functions and powers of our Board include, among others, (i) convening shareholders' annual general meetings and reporting its work to shareholders at such meetings, (ii) declaring dividends, (iii) appointing officers and determining their terms of offices and responsibilities, and (iv) approving the transfer of shares of our Company, including the registering of such shares in our share register.

Terms of Directors and Officers

Our officers are elected by and serve at the discretion of the Board. Each director is not subject to a term of office and holds office until such time as his successor takes office or until the earlier of his death, resignation or removal from office pursuant to the applicable provisions of our memorandum and articles of association. A director will be removed from office automatically 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 of unsound mind; (iii) resigns by notice in writing to our Company; (iv) is prohibited by law or applicable stock exchange rules from being a director; (v) without special leave of absence from our Board, is absent from three consecutive meetings of the Board and the Board resolves that his office be vacated; or (vi) is removed from office pursuant to any other provisions of our post-offering amended and restated memorandum and articles of association.

Board Diversity

The board diversity matrix is set out below.

Board Diversity Matrix (As of March 31, 2022)				
Country of Principal Executive Offices	The People's Republic of China			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	1	7	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction			1	
LGBTQ+			—	
Did Not Disclose Demographic Background			—	

6.D. Employees

We had 696, 799 and 1,154 employees as of December 31, 2019, 2020 and 2021, respectively. The following table sets forth the breakdown of our employees by function as of December 31, 2021.

Function	Number of Employees
Research and development	292
Lab testing operation	221
Sales and marketing	390
Manufacturing and quality control	60
Administration and management	191
Total	1,154

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 regulations in China, we participate in various employee social security plans that are organized by municipal and provincial governments, including pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing funds. 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 have granted, and plan to continue to grant, share-based incentive awards to our employees in the future to incentivize their contributions to our growth and development.

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

6.E. Share Ownership

The following table sets forth information concerning the beneficial ownership of our ordinary shares, as of March 31, 2022, by:

- each of our directors and executive officers; and
- each person known to us to beneficially own more than 5% of our ordinary shares.

The calculations in the table below are based on 453,011,285 ordinary shares issued and outstanding as of March 31, 2022.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant, or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person. The table below excludes (i) 4,272,000 and 7,132,435 ordinary shares held by Genetron Health (Hong Kong) Limited and EVER PRECISE INVESTMENTS LIMITED, respectively, and reserved for the purpose of our employee shareholding platforms established for the restricted shares and options granted under the 2019 Plan, and (ii) 9,950,000 ordinary shares in the form of ADSs deposited to facilitate exercise of awards under the 2019 Plan and the 2019 Scheme as of March 31, 2022, before the corresponding equity awards vest pursuant to the vesting schedule, except when calculating the number of shares underlying share options held by such person or group that are exercisable or RSUs that will become vested within 60 days after March 31, 2022.

	Ordinary Shares Beneficially Owned as of March 31, 2022	
	Number	%*
Executive Officers†		
Sizhen Wang ⁽¹⁾	100,114,120	22.1 %
Hai Yan, Ph.D./M.D. ⁽²⁾	33,153,000	7.3 %
Yuchen Jiao, Ph.D./M.D. ⁽³⁾	7,081,995	1.6 %
Evan Ce Xu	**	**
Yun-Fu Hu	**	**
Fengling Zhang	**	**
Non-Executive Directors		
Xia Wu	—	—
Shan Fu	—	—
Chao Tang	—	—
Dian Kang	**	**
Webster Cavenue	**	**
Wing Kee Lau	**	**
All directors and executive officers as a group	146,577,355	32.4 %
Principal Shareholders		
FHP acting-in-concert group ⁽⁴⁾	75,471,480	16.7 %
CICC entities ⁽⁵⁾	57,824,500	12.8 %
Hai Yan, Ph.D. ⁽²⁾	33,153,000	7.3 %
Tianjin Genetron Jun'an Business Management Partnership (Limited Partnership) ⁽⁶⁾	26,083,650	5.8 %
Vivo Capital Fund IX, L.P. ⁽⁷⁾	37,057,885	8.2 %
EASY BENEFIT INVESTMENT LIMITED and its affiliated entity ⁽⁸⁾	23,401,500	5.2 %

* For each person and group included in this table, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of (i) 453,011,285, being the number of ordinary shares as of March 31, 2022 and (ii) the number of ordinary shares underlying share options held by such person or group that are exercisable within 60 days after March 31, 2022.

- (1) Represents (i) 75,471,480 ordinary shares collectively held by FHP acting-in-concert group, as set forth in note (5) below, (ii) 11,313,140 ordinary shares in the form of ADSs held by Mr. Sizhen Wang, (iii) 8,990,000 ordinary shares held by SUPER SAIL, LLC, a wholly owned limited liability company solely owned by Alliance Trust Company, Trustee of Super E Growth Trust, where Mr. Sizhen Wang is the settlor, and (iv) total of 4,339,500 ordinary shares held by Genetron Discovery Holdings Limited as a record holder, which Mr. Sizhen Wang owns approximately 50.8% equity interests. The registered address of Genetron Discovery Holdings Limited is Harneys Corporate Services Limited, Craigmuir Chambers, P.O. Box 71, Road Town, Tortola, VG 1110, British Virgin Islands.
- (2) Represents 33,153,000 ordinary shares directly held by Mr. Hai Yan.

- (3) Represents (i) (a) 2,359,000 ordinary shares and (b) 1,326,495 ordinary shares in the form of ADSs held by Eugene Health Limited, a British Virgin Islands company wholly owned by Mr. Yuchen Jiao; (ii) 587,500 ordinary shares held by Genetron Discovery Holdings Limited and (iii) 2,809,000 ordinary shares Mr. Yuchen Jiao may purchase upon exercise of options within 60 days of March 31, 2022. Mr. Yuchen Jiao owns approximately 13.5% equity interests in Genetron Discovery Holdings. The registered address of Eugene Health Limited is Craigmuir Chambers, P.O. Box 71, Road Town, Tortola, VG 1110, British Virgin Islands. The registered address of Genetron Discovery Holdings Limited is Craigmuir Chambers, P.O. Box 71, Road Town, Tortola, VG 1110, British Virgin Islands.
- (4) Represents the shares held by FHP act-in-concert group, consisting of (i) 10,814,480 ordinary shares held by FHP Holdings Limited, a British Virgin Islands company wholly owned by Mr. Sizhen Wang, (ii) 33,153,000 ordinary shares held by Mr. Hai Yan, and (iii) a total of 31,504,000 ordinary shares directly held by the FHP-Acting-in-Concert Group (as defined below). On November 19, 2019, FHP Holdings Limited, Mr. Hai Yan, Mr. Weiwu He, Mr. Kevin Ying Hong, Genetron Alliance Holdings Limited and ETP BioHealth II Fund, L.P. entered into a concert party agreement (Mr. Weiwu He, Mr. Kevin Ying Hong, Genetron Alliance Holdings Limited and ETP BioHealth II Fund, L.P., collectively, the “FHP-Acting-in-Concert Group”), pursuant to which the parties agree to (i) always be acting in concert in respect of their respective direct or indirect voting rights at our shareholders’ general meetings and our board meetings, (ii) recognize the controlling position of FHP Holdings Limited; and (iii) act in concert in accordance with FHP Holdings Limited’s opinions in respect of the daily operations and management and the major decision-making of us. The registered address of FHP Holdings Limited is Craigmuir Chambers, P.O. Box 71, Road Town, Tortola, VG 1110, British Virgin Islands. The registered address of Genetron Alliance Holdings Limited is Craigmuir Chambers, P.O. Box 71, Road Town, Tortola, VG 1110, British Virgin Islands. The registered address of ETP BioHealth II Fund, L.P. is Corporation Service Company, 251 Little Falls Drive, in the City of Wilmington, County of New Castle, 19808. In addition, 2,000,000 ordinary shares held by FHP Holdings Limited and a total of 5,800,000 ordinary shares held by certain members of the FHP-Acting-in-Concert Group have been pledged to secure a payment of consideration for purchasing certain shares of Genetron Health from a shareholder of Genetron Health.
- (5) Represents (i) 44,165,500 ordinary shares held by Tianjin Kangyue Business Management Partnership (Limited Partnership)(“Tianjin Kangyue”) and the investment and voting decisions with respect to the Ordinary Shares held by Tianjin Kangyue are made by CICC Kangzhi (Ningbo) Equity Investment Management Co., Ltd. (“CICC Kangzhi”) through an investment committee of CICC Kangrui (No.1) Ningbo Equity Investment Fund Partnership (Limited Partnership) (“CICC Kangrui”), currently consisting of four individuals. CICC Kangrui is a limited partner of Tianjin Kangyue, of which the general partner is CICC Kangzhi. CICC Kangzhi is also a general partner of Tianjin Kangyue and is controlled by CICC Capital Operation Co., Ltd. through contractual arrangements; and (ii) 13,659,000 ordinary shares held by CICC Healthcare Investment Fund, L.P. (“CICC Healthcare Investment”). The general partner of CICC Healthcare Investment is CICC Healthcare Investment Management Limited (“CICC HIM”), which is in turn controlled by CICC Capital (Cayman) Limited (“CICC Capital Cayman”). The investment and voting decisions with respect to the ordinary shares held by CICC Healthcare Investment are made by an investment committee of CICC HIM, currently consisting of three individuals, each of whom is also employed by CICC Capital Operation Co., Ltd. and serves on the investment committee of CICC Kangrui described above. The principal business address of each of the above referenced CICC entities is 9th Floor China World Tower 2, No.1 Jian Guo Men Wai Avenue, Beijing 100004, PRC. Information set forth above is based upon Tianjin Kangyue’s Schedule 13G filing with the SEC on March 14, 2022.

- (6) Represents 26,083,650 ordinary shares held by Tianjin Genetron Jun'an Business Management Partnership (Limited Partnership), or Tianjin Genetron Jun'an, a limited partnership incorporated in the People's Republic of China. The general partner of Tianjin Genetron Jun'an is Zhuhai Jinchang Junying Management Consulting Co., Ltd. The limited partners of Tianjin Genetron Jun'an are Suzhou Fenxiang High-tech Healthcare Entrepreneurship Investment Co. (Limited Partnership) (or Suzhou Fenxiang), Guangxi Yueyin Dade Investment Management Partnership (Limited Partnership) (or Guangxi Yueyin Dade), Shenzhen Fenxiang Precision Medicine Investment Partnership (Limited Partnership) (or Shenzhen Fenxiang), Shanghai Yuanxing Yinshi Equity Investment Partnership (Limited Partnership) (or Shanghai Yuanxing) and Shenzhen Shenshang Xingye Entrepreneurship Investment Fund Partnership (Limited Partnership) (or Shenzhen Shenshang). In accordance with a supplemental limited partnership agreement entered among the general partner and the limited partners of Tianjin Genetron Jun'an, the investment or divestment decision for Tianjin Genetron Jun'an requires the unanimous approval of all limited partners of Tianjin Genetron Jun'an. The general partner of both Suzhou Fenxiang and Shenzhen Fenxiang is Shenzhen Fenxiang Chengzhang Investment Management Limited, whose designated executive representative is Wentao Bai. The general partner of Guangxi Yueyin Dade is Ningbo Meishan Baoshui Gangqu Yueyin Kangtai Equity Investment Partnership (Limited Partnership), whose designated executive representative is Yufen Zheng. The general partner of Shanghai Yuanxing is Ningbo Yuanxing Haozhi Equity Investment Management Partnership (Limited Partnership), whose designated executive representative is Fumin Zhuo. The general partner of Shenzhen Shenshang is Shenzhen City Shenshang Fubo Xingye Fund Management Limited Company, whose designated executive representative is Muxiong Lin. The registered address of Tianjin Genetron Jun'an is Custody No. 0703, Deqin (Tianjin) Registrar Co., Ltd., 113 Building No. 2, Guo Tai Mansion, East Side of Yingbin Avenue, Tianjin Pilot Free Trade Zone, PRC. Information set forth above is based upon Tianjin Genetron Jun'an's Schedule 13G/A filing with the SEC on February 14, 2022.
- (7) Represents (i) 28,574,300 ordinary shares held by Vivo Capital Fund IX, L.P., a limited partnership incorporated in the State of Delaware and (ii) 3,125,000 ordinary shares in the form of 625,000 ADSs held by Vivo Opportunity Fund, L.P., and (iii) 5,358,585 ordinary shares in the form of 1,071,717 ADSs held by Vivo Asia Opportunity Fund, L.P. The general partner of Vivo Capital Fund IX, L.P. is Vivo Capital IX, LLC. The voting members of Vivo Capital IX, LLC are Frank Kung, Shan Fu, Edgar Engleman, Hongbo Lu, Mahendra Shah, Jack Nielsen and Michael Chang, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. Vivo Opportunity, LLC is the general partner of Vivo Opportunity Fund, L.P. The voting members of Vivo Opportunity, LLC are Gaurav Aggarwal, Hongbo Lu, Frank Kung, Michael Chang and Kevin Dai, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. Vivo Asia Opportunity, LLC is the general partner of Vivo Asia Opportunity Fund, L.P. The voting members of Vivo Asia Opportunity, LLC are Hongbo Lu, Frank Kung and Shan Fu, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. The address of principal business office of Vivo Capital IX, LLC, Vivo Opportunity, LLC and Vivo Asia Opportunity, LLC is 192 Lytton Avenue, Palo Alto, CA 94301.
- (8) Represents (i) 20,865,500 ordinary shares held by EASY BENEFIT INVESTMENT LIMITED, and (ii) 2,536,000 ordinary shares held by EASY BEST INVESTMENT LIMITED. Both EASY BENEFIT INVESTMENT LIMITED and EASY BEST INVESTMENT LIMITED are British Virgin Islands companies wholly owned by Mr. KUNG Hung Ka. By virtue of being the controlling shareholder and/or director of each of EASY BENEFIT INVESTMENT LIMITED and EASY BEST INVESTMENT LIMITED, Mr. Kung Hung Ka may be deemed to have sole voting and dispositive power with respect to these shares. The registered address of each of EASY BENEFIT INVESTMENT LIMITED and EASY BEST INVESTMENT LIMITED is OMC Chambers, Wickhams Cay 1, Road Town, Tortola, British Virgin Islands. Information set forth above is based upon Easy Benefit Investment Limited's Schedule 13G filing with the SEC on April 28, 2021.

To our knowledge, as of March 31, 2022, a total of 219,561,040 ordinary shares are held by one record holder in the United States, representing approximately 48.5% of our total outstanding shares. The holder is the depository of our ADS program. In addition, 18.7% of our outstanding ordinary shares are held by record holders in the United States.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major Shareholders

Please refer to “Item 6. Directors, Senior Management and Employees—6.E. Share Ownership.” The company’s major shareholders do not have different voting rights than the other shareholders.

7.B. Related Party Transactions

Employment Agreements

See “Item 6. Directors, Senior Management and Employees—6.B. Compensation—Employment Agreements and Indemnification Agreements” for a description of the employment agreements we have entered into with our senior executive officers.

Share Incentives

See “Item 6. Directors, Senior Management and Employees—6.B. Compensation—Share Incentive Plan” for a description of share options we have granted to our directors, officers and other individuals as a group.

Contractual Arrangements

See “Item 4. Information on the Company—4.C. Organizational Structure—Contractual Arrangements with the VIEs and their Shareholders” for a description of the contractual arrangements by and among our PRC Subsidiaries, the VIEs and the shareholders of the VIEs.

Other Related Party Transactions

Transaction with Edigene (Beijing) Inc.

We provide gene sequencing services to Edigene (Beijing) Inc., or Edigene, which is an affiliate of Mr. Sizhen Wang. The amounts for the provision of the service were RMB1.2 million (US\$0.2 million) in 2021, and as of December 31, 2021, the amounts due from Edigene were RMB0.6 million (US\$0.1 million).

Transaction with Beijing Aboluoba Health Management Co.,Ltd.

We provided gene services to Beijing Aboluoba Health Management Co.,Ltd., which is an affiliate of the wife of Mr. Weihu He, our Chairman of the Board until June 30, 2021.

Transaction with Hangzhou ImmuQuad Biotechnologies, LLC

We purchased goods and services from Hangzhou ImmuQuad Biotechnologies, LLC, which is an associate of our Group. The amounts for the purchase were RMB87,000 (US\$14,000) in 2021, and as of December 31, 2021, the amounts due to Hangzhou ImmuQuad Biotechnologies, LLC were RMB3,000 (US\$500).

7.C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

8.A. Consolidated Statements and Other Financial Information

We have appended consolidated financial statements filed as part of this annual report.

Legal and Administrative Proceedings

We are currently not a party to any material legal or administrative 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 a substantial cost and diversion to our resources, including our management's time and attention. For risks relating to legal and administrative proceedings against us, please see "Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Operations—Allegations or lawsuits against us or our management may harm our reputation and business."

Dividend Policy

We have not previously declared or paid cash dividends and we have no plan to declare or pay any dividends in the near future on our shares or the ADSs representing our ordinary shares. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business.

We are a holding company incorporated in the Cayman Islands. We rely principally on dividends from our PRC Subsidiaries for our cash requirements, including any payment of dividends to our shareholders. PRC regulations may restrict the ability of our PRC Subsidiaries to pay dividends to us. See "Item 4. Information of the Company—4.B. Business Overview—Regulations—PRC Regulations—Regulations Related to Dividend Distribution."

Our Board has discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, our shareholders may, subject to the provisions of our articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board. Under Cayman Islands law, a Cayman Islands exempt company may pay a dividend out of either profit or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. Even if our Board decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the Board may deem relevant. If we pay any dividends on our ordinary shares, we will pay those dividends which are payable in respect of the ordinary shares underlying the ADSs to the depository, as the registered holder of such ordinary shares, and the depository then will pay such amounts to the ADS holders in proportion to the ordinary shares underlying the ADSs held by such ADS holders, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. See "Item 12. Description of Securities Other Than Equity Securities—12.D. American Depositary Shares."

8.B. Significant Changes

Except as otherwise disclosed in this report, we have not experienced any significant changes since the date of the annual financial statements included herein.

ITEM 9. THE OFFER AND LISTING

9.A. Offering and Listing Details

Our ADSs have been listed on the Nasdaq Global Market since June 19, 2020 under the symbol "GTH." Each ADS represents five ordinary shares, par value US\$0.00002 per share.

9.B. Plan of Distribution

Not applicable.

9.C. Markets

Our ADSs have been listed on the Nasdaq Global Market since June 19, 2020 under the symbol “GTH.”

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

10.A. Share Capital

Not applicable.

10.B. Memorandum and Articles of Association

We incorporate by reference into this annual report our fourth amended and restated memorandum and articles of association, the form of which was initially filed as Exhibit 3.2 to our registration statement on Form F-1 (File No. 333-234805), as amended, filed with the SEC on June 15, 2020. Our members adopted our amended and restated memorandum and articles of association by a special resolution on January 14, 2020, which became effective immediately prior to completion of our initial public offering of ADSs representing our ordinary shares.

The following are summaries of material provisions of our fourth amended and restated memorandum and articles of association and the Companies Act (as amended) insofar as they relate to the material terms of our ordinary shares.

Registered Office and Objects

Our registered office in the Cayman Islands is at the offices of Walkers Corporate Limited, 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands.

According to Clause 3 of our fourth amended and restated memorandum of association, the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by any law as provided by Section 7(4) of the Companies Act (as amended) of the Cayman Islands.

Board of Directors

See “Item 6. Directors, Senior Management and Employees.”

Ordinary Shares

General. As of March 31, 2022, our authorized share capital is US\$50,000 divided into 2,500,000,000 ordinary shares, with a par value of US\$0.00002 each. Holders of ordinary shares have the same rights except for voting and conversion rights. All of our issued and outstanding ordinary shares are fully paid and non-assessable. Certificates representing the ordinary shares are issued in registered form. We may not issue share to bearer. Our shareholders who are nonresidents of the Cayman Islands may freely hold and transfer their ordinary shares.

Dividends. The holders of our ordinary shares are entitled to such dividends as may be declared by our Board subject to our fourth amended and restated memorandum and articles of association and the Companies Act (as amended). In addition, our shareholders may, subject to the provisions of our articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Our fourth amended and restated memorandum and 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 determines 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 in accordance with the Companies Act. No dividend may be declared and paid unless our directors determine that, immediately after the payment, we will be able to pay our debts as they become due in the ordinary course of business and we have funds lawfully available for such purpose.

Voting Rights. In respect of all matters subject to a shareholders' vote, each ordinary share is entitled to one vote for each ordinary share registered in his or her name on our register of members. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one shareholder.

A quorum required for a meeting of shareholders consists of the holders of ordinary shares being not less than one-half of the votes attaching to the issued and outstanding shares entitled to vote at general meetings present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our fourth amended and restated memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we will specify the meeting as such in the notices calling it, and the annual general meeting will be held at such time and place as may be determined by our Board. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Shareholders' annual general meetings and any other general meetings of our shareholders may be called by a majority of our Board or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than ten (10) percent of the votes attaching to the issued and outstanding shares entitled to vote at general meetings, in which case the directors are obliged to call such meeting and to put the resolutions so requisitioned to a vote at such meeting; however, our fourth amended and restated memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders. Advance notice of at least seven (7) calendar days is required for the convening of our annual general meeting and other general meetings unless such notice is waived in accordance with our fourth amended and restated memorandum and articles of association.

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 by those shareholders entitled to vote who are present in person or by proxy at a general meeting, while a special resolution also requires the affirmative vote of no less than two-thirds of the votes attaching to the ordinary shares cast by those shareholders entitled to vote who are present in person or by proxy at a general meeting. A special resolution will be required for important matters such as a change of name or making changes to our fourth amended and restated memorandum and articles of association.

Transfer of Ordinary Shares. Subject to the restrictions in our fourth amended and restated memorandum and articles of association as set out below, 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.

Our Board may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have lien. Our Board may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our Board may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four;

- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Nasdaq may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within three 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 may, after compliance with any notice required of the Nasdaq, be suspended and the register or members closed at such times and for such periods as our Board may from time to time determine, *provided, however*, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year as our Board may determine.

Liquidation. On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares), if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our Company for unpaid calls or otherwise. 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 in proportion to the par value of the shares held by them. Any distribution of assets or capital to a holder of ordinary share will be the same in any liquidation event.

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

Redemption, Repurchase and Surrender of Ordinary Shares. We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders thereof, on such terms and in such manner as may be determined, before the issue of such shares, by our Board or by an ordinary resolution of our shareholders. Our Company may also repurchase any of our shares provided that the manner and terms of such purchase have been approved by our Board or by ordinary resolution of our shareholders, or are otherwise authorized by our fourth amended and restated memorandum and articles of association. Under the Companies Act (as amended), the redemption or repurchase of any share may be paid out of our Company's profits or out of the proceeds of a fresh issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if the company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act (as amended) no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding, or (c) if the company has commenced liquidation. In addition, our Company may accept the surrender of any fully paid share for no consideration.

Variations of Rights of Shares. If at any time our share capital is divided into different classes or series 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 a majority of the holders of the issued shares of that class or series or with the sanction of a special resolution 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.

Inspection of Books and Records. Holders of our ordinary shares 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.

Limitations on the Rights to Own Ordinary Shares. There are no limitations under the laws of the Cayman Islands or under the fourth amended and restated memorandum and articles of association that limit the right of non-resident or foreign owners to hold or vote ordinary shares.

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

Our fourth amended and restated memorandum and articles of association also authorizes our Board to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our Board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Anti-Takeover Provisions. Some provisions of our fourth amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our Company or management that shareholders may consider favorable, including provisions that authorize our Board to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

Exempted Company. We are an exempted company with limited liability under the Companies Act (as amended). The Companies Act (as amended) 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 an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 30 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- 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.

10.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” or elsewhere in this annual report on Form 20-F.

10.D. Exchange Controls

The Cayman Islands currently has no exchange control regulations or currency restrictions. For exchange control regulations or currency restrictions in China, see “Item 4. Information on the Company—4.B. Business Overview—Regulations—PRC Regulations—Regulations Related to Foreign Exchange.”

10.E. Taxation

The following discussion of Cayman Islands, PRC and United States federal income tax consequences of the ownership and disposition of the ADSs or 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 discussion does not deal with all possible tax consequences relating to the ownership and disposition of the ADSs or ordinary shares, such as the tax consequences under state, local and other tax laws. To the extent that the discussion relates to matters of Cayman Islands tax law, it represents the opinion of Walkers (Hong Kong), our Cayman Islands counsel. To the extent that the discussion relates to matters of PRC tax law, it represents the opinion of Shihui Partners, our PRC legal counsel.

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 us or holders of our ADSs or ordinary shares 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 not party to any double tax treaties that 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 the ADSs or ordinary shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the ADSs or ordinary shares, nor will gains derived from the disposal of the ADSs or ordinary shares be subject to Cayman Islands income or corporation tax.

PRC Taxation

Under the PRC EIT Law, which became effective on January 1, 2008 and was amended on December 29, 2018, an enterprise established outside the PRC with “de facto management bodies” within the PRC 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 rules to the PRC EIT Law, a “de facto management body” is defined as a body that has material and overall management and control over the manufacturing and business operations, personnel and human resources, finances and properties of an enterprise.

In addition, the SAT Circular 82 issued by the SAT in April 2009 specifies that certain offshore incorporated enterprises controlled by PRC enterprises or PRC enterprise groups will be classified as PRC resident enterprises if the following are located or resident in the PRC: (a) senior management personnel and departments that are responsible for daily production, operation and management; (b) financial and personnel decision-making bodies; (c) key properties, accounting books, company seal, minutes of board meetings and shareholders' meetings; and (d) half or more of the senior management or directors having voting rights. 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 key assets are its ownership interests in its subsidiaries, 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. For similar reasons, we believe our other entities outside China are not PRC resident enterprises either. 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 (including our ADS holders). In addition, nonresident enterprise shareholders (including our ADS holders) may be subject to PRC tax on at a rate of 10% gains realized on the sale or other disposition of ADSs or 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 (including our ADS holders) and any gain realized on the transfer of ADSs or 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 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 "Item 3. Key Information—3.D. Risk Factors—Risks Related to Doing Business in the PRC—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 or ADS holders."

Material U.S. Federal Income Tax Considerations

The following are material U.S. federal income tax consequences to the U.S. Holders described below of the ownership and disposition of the ADSs or ordinary shares, but it does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to hold ADSs or ordinary shares. This discussion applies only to a U.S. Holder that holds the ADSs or ordinary shares as capital assets for U.S. federal income tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including the alternative minimum tax, the Medicare contribution tax consequences, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities that use a mark-to-market method of tax accounting;
- persons holding ADSs or ordinary shares as part of a straddle, conversion transaction, integrated transaction or similar transaction;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt entities, "individual retirement accounts" or "Roth IRAs";
- persons that receive ADSs or ordinary shares as compensation for the performance of services;
- persons that own or are deemed to own 10% or more of our stock by vote or value; or

- persons holding ADSs or ordinary shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes owns ADSs or ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships owning ADSs or ordinary shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of ADSs and ordinary shares.

This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations, and the income tax treaty between the United States and the PRC, or the Treaty, all as of the date hereof, any of which is subject to change, possibly with retroactive effect. This discussion assumes that each obligation under the deposit agreement and any related agreement will be performed in accordance with its terms.

For purposes of this discussion, a “U.S. Holder” is a person eligible for Treaty benefits that is, for U.S. federal income tax purposes, is a beneficial owner of ADSs or ordinary shares and:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

Treasury regulations that apply to taxable years beginning on or after December 28, 2021 (the “Foreign Tax Credit Regulations”) may in some circumstances prohibit a U.S. person from claiming a foreign tax credit with respect to certain non-U.S. taxes that are not creditable under applicable income tax treaties. Accordingly, U.S. investors that are not eligible for Treaty benefits should consult their tax advisers regarding the creditability or deductibility of any PRC taxes imposed on dividends on, or dispositions of, the ADSs or ordinary shares. This discussion does not apply to investors in this special situation.

In general, a U.S. Holder that owns ADSs will be treated as the owner of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying ordinary shares represented by those ADSs.

This discussion does not address the effects of any state, local or non-U.S. tax laws, or any U.S. federal taxes other than income taxes (such as U.S. federal estate or gift tax consequences). U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ADSs or ordinary shares in their particular circumstances.

Passive Foreign Investment Company

In general, a non-U.S. corporation is a passive foreign investment company, or a PFIC, for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the average value of its assets (generally determined on a quarterly basis) consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that owns (or is treated as owning for U.S. federal income tax purposes), directly or indirectly, at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and certain gains. Cash is generally a passive asset for these purposes. Goodwill is treated as an active assets to the extent attributable to activities that produce active income.

Based on the composition of our income and assets and the estimated value of our assets, including goodwill, we believe that we were not a PFIC for our 2021 taxable year. However, our PFIC status for any taxable year is an annual determination that depends on the composition of our income and assets and the value of our assets from time to time. We hold a substantial amount of cash and while that continues to be the case our PFIC status for any taxable year will depend primarily on the average value of our goodwill. The value of our goodwill may be determined, in large part, by reference to our market capitalization. Because our market capitalization has been volatile and declined substantially in recent months, if the value of our goodwill is determined by reference to our market capitalization and the market price of the ADSs does not increase sufficiently, there is a significant risk that we will be a PFIC for our taxable year 2022, and possibly future taxable years. Moreover, it is not entirely clear how the contractual arrangements between us and the VIEs will be treated for purposes of the PFIC rules, and we may be or become a PFIC if the VIEs are not treated as owned by us for these purposes. For these reasons, there can be no assurance that we will not be a PFIC for any taxable year.

If we are a PFIC for any taxable year and any entity in which we own or are treated as owning equity interests (including the VIEs and their subsidiaries) is also a PFIC (any such entity, a “Lower-tier PFIC”), a U.S. Holder will be deemed to own a proportionate amount (by value) of the shares of each Lower-tier PFIC and will be subject to U.S. federal income tax according to the rules described in the subsequent paragraph on (i) certain distributions by a Lower-tier PFIC and (ii) dispositions of shares of Lower-tier PFICs, in each case as if the U.S. Holder held such shares directly, even though the U.S. Holder will not receive the proceeds of those distributions or dispositions.

In general, if we are a PFIC for any taxable year during which a U.S. Holder holds ADSs or ordinary shares, gain recognized by such U.S. Holder on a sale or other disposition (including certain pledges) of its ADSs or ordinary shares will be allocated ratably over that U.S. Holder’s holding period. The amounts allocated to the taxable year of the sale or disposition and to any taxable year before we became a PFIC will be taxed as ordinary income. The amount allocated to each other taxable year will be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge will be imposed on the resulting tax liability for each such year. Furthermore, to the extent that distributions received by a U.S. Holder in any taxable year on its ADSs or ordinary shares exceed 125% of the average of the annual distributions on the ADSs or ordinary shares received during the preceding three taxable years or the U.S. Holder’s holding period for the ADSs or ordinary shares, whichever is shorter, the excess distributions will be subject to taxation in the same manner. If we are a PFIC for any taxable year during which a U.S. Holder owns ADSs or ordinary shares, we will generally continue to be treated as a PFIC with respect to the U.S. Holder for all succeeding years during which the U.S. Holder owns ADSs or ordinary shares, even if we cease to meet the threshold requirements for PFIC status, unless the U.S. Holder makes a timely “deemed sale” election, in which case any gain on the deemed sale will be taxed under the PFIC rules described above.

Alternatively, if we are a PFIC and if the ADSs are “regularly traded” on a “qualified exchange,” as defined in applicable Treasury regulations, a U.S. Holder of ADSs can make a mark-to-market election that will result in tax treatment different from the general tax treatment for PFICs described in the preceding paragraph. The ADSs will be treated as “regularly traded” for any calendar year in which more than a *de minimis* quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter. Nasdaq Global Market, where our ADSs are listed, is a qualified exchange for this purpose, but there can be no assurance that our ADSs will be regularly traded for any relevant period. U.S. Holders will not be able to make a mark-to-market election with respect to Lower-tier PFICs, if any. Accordingly, if we are a PFIC for any taxable year, a U.S. Holder that makes the mark-to-market election may continue to be subject to the general PFIC rules with respect to such U.S. Holder’s indirect interest in any Lower-tier PFICs. If a U.S. Holder makes the mark-to-market election, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year in which we are a PFIC over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder’s tax basis in the ADSs will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of ADSs in a year when the Company is a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election, with any excess treated as capital loss). If a U.S. Holder makes the mark-to-market election, distributions paid on ADSs will be treated as discussed under “—Taxation of Distributions” below, but subject to the discussion in the immediately preceding paragraph.

If we are a PFIC (or with respect to a particular U.S. Holder are treated as a PFIC) for a taxable year in which we pay a dividend or for the prior taxable year, the favorable tax rate described below with respect to dividends paid to certain non-corporate U.S. Holders will not apply.

We do not intend to provide the information that would enable U.S. Holders to make a “qualified electing fund election,” which would result in alternate treatment if we are a PFIC for any taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder owns any ADSs or ordinary shares, the U.S. Holder will generally be required to file annual reports with the Internal Revenue Service.

U.S. Holders should consult their tax advisers regarding the determination of whether we are a PFIC for any taxable year and the potential application of the PFIC rules to their ownership of ADSs or ordinary shares (including the availability and advisability of making either the deemed sale or mark-to-market election described above if we are a PFIC for any taxable year).

Taxation of Distributions

This discussion is subject to the discussion under “—Passive Foreign Investment Company” above. Distributions paid on the ADSs or ordinary shares, other than certain pro rata distributions of ADSs or ordinary shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, it is expected that distributions generally will be reported to U.S. Holders as “dividends” for U.S. federal income tax purposes. Dividends will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Subject to applicable limitations, dividends paid on our ADSs to certain non-corporate U.S. investors are taxable at the favorable rates applicable to long-term capital gains for so long as our ADSs are listed on the Nasdaq Global Market or if in the future we are eligible for benefits under the Treaty. However, as described above the favorable rate does not apply if we are (or are treated with respect to a U.S. Holder as) a PFIC, for the year the dividend is paid or the preceding year. Non-corporate U.S. Holders should consult their tax advisers to determine whether the favorable rate will apply to dividends they receive and whether they are subject to any special rules that limit their ability to be taxed at this favorable rate.

Dividends will be included in a U.S. Holder’s income generally on the date of the U.S. Holder’s, or in the case of ADSs, the Depositary’s, receipt. The amount of any dividend income paid in currency other than U.S. dollars will be the U.S. dollar amount calculated by reference to the spot rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars on that date. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the amount received. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Dividends will be treated as foreign-source income for foreign tax credit purposes. As described in “—PRC Taxation,” dividends paid by the Company may be subject to PRC withholding tax. For U.S. federal income tax purposes, the amount of the dividend income will include amounts withheld in respect of any PRC withholding tax. Subject to applicable limitations, which vary depending upon the U.S. Holder’s circumstances, PRC taxes withheld from dividend payments (at a rate not exceeding the applicable rate provided in the Treaty) generally will be creditable against the U.S. Holder’s U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign tax credits in their particular circumstances. In lieu of claiming a credit, a U.S. Holder may elect to deduct such PRC taxes in computing its taxable income, subject to applicable limitations. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or Other Disposition of ADSs or ordinary shares

This discussion is subject to the discussion under “—Passive Foreign Investment Company” above.

For U.S. federal income tax purposes, gain or loss realized on the sale or other taxable disposition of ADSs or ordinary shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ADSs or ordinary shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the ADSs or ordinary shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars.

As described in “—PRC Taxation” above, gains on the sale of ADSs or ordinary shares may be subject to PRC taxes if we are treated as a PRC resident enterprise for PRC tax purposes. Under the Code, capital gains of U.S. persons are generally treated as U.S.-source income. However, a U.S. Holder may be able to elect to treat the gain as foreign-source income under the Treaty and claim foreign tax credit in respect of any PRC tax on dispositions. The Foreign Tax Credit Regulations generally preclude a U.S. Holder from claiming a foreign tax credit with respect to PRC income taxes on gains from dispositions of ADSs or ordinary shares if the U.S. Holder does not elect to apply the benefits of the Treaty. However, in that case it is possible that any PRC taxes on disposition gains may either be deductible or reduce the amount realized on the disposition. The rules governing foreign tax credits and deductibility of foreign taxes are complex. U.S. Holders should consult their tax advisers regarding the consequences of the imposition of any PRC tax on disposition gains, including the Treaty’s resourcing rule, any reporting requirements with respect to a Treaty-based return position and the creditability or deductibility of the PRC tax on disposition gains in their particular circumstances (including any applicable limitations).

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds from the sale or exchange of our ADSs or ordinary shares, that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding, generally on Internal Revenue Service Form W-9. Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder’s U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the Internal Revenue Service.

Certain U.S. Holders who are individuals (or certain specified entities) may be required to report information relating to their ownership of ADSs or ordinary shares, or non-U.S. accounts through which ordinary shares are held. U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to the ADSs or ordinary shares.

10.F. Dividends and Paying Agents

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

We previously filed with the SEC registration statement on Form F-1 (File No. 333-234805), as amended to register our ordinary shares in relation to our initial public offering. We also filed with the SEC related registration statement on Form F-6 (File No. 333-235249) to register the ADSs and registration statement on Form S-8 (File No. 333-252371) to register our securities to be issued under 2019 Genetron Health Share Incentive Plan and 2019 Genetron Health Share Incentive Scheme.

We are subject to the periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F within four months after the end of each fiscal year. Copies of reports and other information, when so filed with the SEC, can be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents, upon payment of a duplicating fee, by writing to the SEC. The SEC also maintains a web site at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system. As a foreign private issuer, we are exempt from the rules of the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will furnish The Bank of New York Mellon, the depository of our ADSs, with our annual reports, which will include a review of operations and annual audited consolidated financial statements prepared in conformity with IFRS, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depository will make such notices, reports and communications available to holders of ADSs and, upon our request, will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depository from us.

10.I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

Our exposure to interest rate risk primarily relates to the interest income generated by excess cash, which is mostly held in interest-bearing bank deposits. We have not used any derivative financial instruments to manage our interest risk exposure. Interest-earning instruments carry a degree of interest rate risk. We have not been exposed, nor do we anticipate being exposed, to material risks due to changes in interest rates. However, our future interest income may be lower than expected due to changes in market interest rates.

Foreign exchange risk

Substantially all of our net revenues and expenses are denominated in Renminbi. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge exposure to such risk. Although our exposure to foreign exchange risks should be limited in general, the value of your investment in the ADSs will be affected by the exchange rate between U.S. dollar and Renminbi because the value of our business is effectively denominated in RMB, while the ADSs representing our ordinary shares will be traded in U.S. dollars.

The value of the Renminbi against the U.S. dollar and other currencies is affected by changes in China's political and economic conditions and by China's foreign exchange policies, among other things. In July 2005, the PRC government changed its decades-old policy of pegging the value of the Renminbi to the U.S. dollar, and the Renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation subsided and the exchange rate between the Renminbi and the U.S. dollar remained within a narrow band. Since June 2010, the Renminbi has fluctuated against the U.S. dollar, at times significantly and unpredictably. While appreciating approximately by 7% against the U.S. dollar in 2017, the Renminbi in 2018 depreciated approximately by 5% against the U.S. dollar. Since October 1, 2016, the RMB has joined the International Monetary Fund (IMF)'s basket of currencies that make up the Special Drawing Right (SDR), along with the U.S. dollar, the Euro, the Japanese yen and the British pound. With the development of the foreign exchange market and progress towards interest rate liberalization and Renminbi internationalization, the PRC government may in the future announce further changes to the exchange rate system and there is no guarantee that the RMB will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the Renminbi and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into Renminbi for our operations, appreciation of 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 or ADSs, servicing our outstanding debt, or for other business purposes, appreciation of the U.S. dollar against the Renminbi would reduce the U.S. dollar amounts available to us.

Inflation risk

Since our inception, inflation in China has not materially impacted our results of operations. According to the National Bureau of Statistics of China, the year-over-year percent change in the consumer price index for 2019, 2020 and 2021 were increases of 2.9%, 2.5% and 0.9%, respectively. Although we have not in the past been materially affected by inflation since our inception, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

Credit risk

Credit risk primarily arises from wealth management products, cash and cash equivalents, trade and other receivables, amounts due from related parties and contract assets. The maximum exposure to credit risk is represented by the carrying amount of each financial asset in the balance sheets.

As of December 31, 2021, most of our cash and cash equivalents and wealth management products were held at state-owned or reputable financial institutions in the PRC. There has been no recent history of default related to these financial institutions. We believe that these financial institutions are of high credit quality, and we continually monitor the credit worthiness of these financial institutions.

Trade receivables and contract assets are typically unsecured and are derived from revenue earned directly from customers. We have not experienced any significant recoverability issue with respect to trade receivables and contract assets. Our historical experience in collection of receivables falls within the recorded allowances, and we believe that we have made adequate provision for uncollectible receivables.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

12.A. Debt Securities

Not applicable.

12.B. Warrants and Rights

Not applicable.

12.C. Other Securities

Not applicable.

12.D. American Depositary Shares

Fees and Expenses

*Persons depositing or withdrawing shares
or ADS holders must pay:*

- \$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)
- \$0.05 (or less) per ADS
- A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs
- \$0.05 (or less) per ADS per calendar year
- Registration or transfer fees
- Expenses of the depositary
- Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes
- Any charges incurred by the depositary or its agents for servicing the deposited securities

For:

- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to ADS holders
- Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
- Depositary services
- Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
- Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement)
- Converting foreign currency to U.S. dollars
- As necessary
- As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payments by Depositary

In 2021, we did not receive any cash payment from The Bank of New York Mellon, the depositary bank for our ADR program.

PART II

ITEM 13. ITEM DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

14.A. – 14.D. Material Modifications to the Rights of Security Holders

See “Item 10. Additional Information” for a description of the rights of shareholders, which remain unchanged.

14.E. Use of Proceeds

The following “Use of Proceeds” information relates to the registration statement on Form F-1, as amended (File No. 333-234805) in relation to our initial public offering, which was declared effective by the SEC on June 18, 2020. In June 2020, we completed our initial public offering in which we issued and sold an aggregate of 16,000,000 ADSs, representing 80,000,000 ordinary shares, resulting in net proceeds to us of approximately US\$234.0 million, net of the underwriting discounts and commissions and other fees paid or payable by us in connection with the offering.

For the period from the effective date of the registration statement on Form F-1 to December 31, 2021, we used US\$155.2 million of the net proceeds received from our initial public offering primarily for general corporate and working capital purposes. We still intend to use the remainder of the proceeds from our initial public offering as disclosed in our registration statements on Form F-1.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report, as required by Rule 13a-15(b) under the Exchange Act.

Based upon that evaluation, our management has concluded that, as of December 31, 2021, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act was recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

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 defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As required by Rule 13a-15(c) of the Exchange Act, our management conducted an evaluation of our Company's internal control over financial reporting as of December 31, 2021 based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of our internal control over financial reporting to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Remediation of Previously Reported Material Weaknesses in Internal Control over Financial Reporting

As described in our previous annual report on Form 20-F for the fiscal year ended December 31, 2020, our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting as of December 31, 2020. As defined in standards established by the PCAOB, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The two material weaknesses that were identified in our internal control over financial reporting as of December 31, 2020 related to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of IFRS and reporting requirements set forth by the SEC to address complex IFRS technical accounting issues, and to prepare and review the consolidated financial statements and related disclosures in accordance with IFRS and SEC reporting requirements; and (ii) our lack of formal and effective period-end financial closing policies and procedures.

To remediate our identified material weaknesses, we have implemented the following measures to improve our internal control over financial reporting:

- hired more qualified accounting personnel, with relevant IFRS and SEC reporting experience and qualifications to strengthen the financial reporting function and set up a financial and systematic control framework;
- implemented regular and continuous IFRS accounting and financial reporting training programs for our accounting and financial reporting personnel;
- set up an internal audit function as well as engaged an external consulting firm to assist us with assessment and improvement of overall internal control so as to fulfill our Sarbanes-Oxley compliance obligations; and
- prepared comprehensive accounting policies, manuals and closing procedures to optimize our period-end financial closing process and ensure consolidated financial statements and related disclosures are in compliance with IFRS and SEC reporting requirements.

As of result of these efforts, our management concluded that the material weaknesses had been remediated as of December 31, 2021.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm, PricewaterhouseCoopers Zhong Tian LLP has audited the effectiveness of our internal control over financial reporting as of December 31, 2021 as stated in its report, which appears on page F-2 of this annual report on Form 20-F.

Changes in Internal Control over Financial Reporting

Other than as described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this annual report on Form 20-F that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16.A. AUDIT COMMITTEE FINANCIAL EXPERT

Our Board has determined that Mr. Wing Kee Lau, an independent director and the chairperson of our audit committee, qualifies as an “audit committee financial expert” within the meaning of the SEC rules and in accordance with applicable Nasdaq Global Market standards. Mr. Wing Kee Lau satisfies the “independence” requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq Global Market standards.

16.B. Code of Ethics

Our Board has adopted a code of business conduct and ethics that applies to all of our directors, officers, employees, including certain provisions that specifically apply to our principal executive officer, principal financial officer, principal accounting officer or controller and any other persons who perform similar functions for us. We have filed our code of business conduct and ethics as Exhibit 99.1 of our registration statement on Form F-1 (File No. 333-234805), as amended, filed with the SEC on November 21, 2019 and posted a copy of our code of business conduct and ethics on our website at <https://ir.genetronhealth.com/>. We hereby undertake to provide to any person without charge, a copy of our code of business conduct and ethics within ten working days after we receive such person’s written request.

16.C. Principal Accountant Fees and Services

Auditor Fees

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by PricewaterhouseCoopers Zhong Tian LLP, our independent registered public accounting firm, for the periods indicated.

Services	Year Ended December 31,	
	2020	2021
	RMB	RMB
	(in thousands)	
Audit Fees(1)	8,809	11,226
Audit-Related Fees(2)	—	1,439
Tax Fees(3)	—	—
Other Fees(4)	—	—
Total	8,809	12,665

(1) Audit fees refer to the aggregate fees billed in each of the fiscal periods listed for professional services rendered by our principal auditors for the audit of our annual consolidated financial statements and our internal controls over financial reporting as well as assistance with and review of documents filed with the SEC.

(2) Audit-related fees refer to the aggregate fees billed for professional services rendered by our principal auditors for the assurance and related services, which were not included under Audit Fees above.

(3) Tax fees refer to fees incurred from professional services related to tax compliance.

(4) Other fees refer to fees incurred from professional services related to training, advisory and assurance for corporate and social responsibility reporting and professional services related to tax advice.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by PricewaterhouseCoopers Zhong Tian LLP, our independent registered public accounting firm, including audit services and audit-related services as described above, other than those for de minimis services which are approved by the audit committee prior to the completion of the audit.

16.D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

16.E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any “affiliated purchaser,” as defined in Rule 10b-18(a)(3) of the Exchange Act, purchased any of our equity securities during the period covered by this annual report.

16.F. Change in Registrant’s Certifying Accountant

Not applicable.

16.G. Corporate Governance

Rule 5615 of the Nasdaq Rules permits a foreign private issuer like our Company to follow home country practice in certain corporate governance matters. We choose to follow certain home country practices in lieu of certain corporate government requirements set forth in the Rule 5600 series of the Nasdaq Rules. As such, our shareholders may be afforded less protection than they otherwise would under the Nasdaq Global Market corporate governance listing standards applicable to U.S. domestic issuers. Specifically, we relied on home country practice exemption with respect to

- Rule 5605(b)(1) of the Nasdaq Rules, which requires a Nasdaq-listed company to establish a board of directors with majority of the board comprised of independent directors. We currently do not have a majority independent board;
- Rule 5605(d)(2) of the Nasdaq Rules, which requires a Nasdaq-listed company to establish a compensation committee comprised entirely of independent directors. Currently, one out of three members of the compensation committee is an independent director;
- Rule 5605(e)(1) of the Nasdaq Rules, which requires a Nasdaq-listed company to nominate director nominees either by a majority independent board or by a nominations committee comprised solely of independent directors. We currently do not have a majority independent board or a nominations committee comprised solely of independent directors;
- Rule 5250(b)(3) of the Nasdaq Rules, which requires a Nasdaq-listed company to disclose third party director and nominee compensation no later than when the companies files its next Form 20-F. We did not disclose such information on individual basis in our annual report on the Form of 20-F for the year of 2020 and 2021; and
- Rule 5620(a) of the Nasdaq Rules, which requires a Nasdaq-listed company to hold an annual meeting of Shareholders no later than one year after the end of the company’s fiscal year-end. We did not hold an annual shareholders meeting in 2021. We may, however, hold an annual shareholder meeting in the future if there are significant issues that require shareholders’ approvals.

We elected to follow home country practice exemption and be exempt from the requirements to obtain shareholder approval for (1) certain acquisitions of the stock or assets of another company under Rule 5635(a) of the Nasdaq Rules, (2) the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended under Rule 5635(c) of the Nasdaq Rules, and (3) the issuance of 20% or more of its outstanding ordinary shares under Rule 5635(d) of the Nasdaq Rules.

Walkers (Hong Kong), our Cayman Islands counsel, has provided a letter to the Nasdaq Stock Market certifying that under Cayman Islands law, we are not required to comply with abovementioned requirements

We may also opt to rely on additional home country practice exemptions in the future. See “Item 3. Key Information—3. D. Risk Factors—Risks Related to the ADSs—As an exempted 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 Stock Market corporate governance listing standards; these practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq Stock Market corporate governance listing standards.”

16.H. Mine Safety Disclosure

Not applicable.

16.I. 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

Our consolidated financial statements are included at the end of this annual report.

ITEM 19. EXHIBITS

Exhibit Number	Description of Document
1.1	Fourth Amended and Restated Memorandum and Articles of Association (incorporated by reference to Exhibit 3.2 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.1	Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.2	Form of Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.2 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.3	Form of Deposit Agreement between the Registrant, the depositary and holders of the American Depositary Shares (incorporated by reference to Exhibit 4.3 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.4	Amended and Restated Shareholders Agreement by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, certain investors of Genetron Holdings Limited and other parties named therein dated November 19, 2019 (incorporated by reference to Exhibit 4.4 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.5	Amendment to Amended and Restated Shareholders Agreement dated November 19, 2019 by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, certain investors of Genetron Holdings Limited and other parties named therein dated January 14, 2020 (incorporated by reference to Exhibit 4.5 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.6	Amendment to Amended and Restated Shareholders Agreement dated November 19, 2019 by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, certain investors of Genetron Holdings Limited and other parties named therein dated May 28, 2020 (incorporated by reference to Exhibit 4.6 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
2.7	Description of Securities (incorporated by reference to Exhibit 2.7 from our annual report on Form 20-F for the fiscal year ended December 31, 2020 (File No. 001-39328) with the SEC on April 9, 2021).
4.1	2019 Genetron Health Share Incentive Plan (incorporated by reference to Exhibit 10.1 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
4.2	2019 Genetron Health Share Incentive Scheme (incorporated by reference to Exhibit 10.2 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
4.3	Form of Indemnification Agreement with the Registrant's directors (incorporated by reference to Exhibit 10.3 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
4.4	Form of Employment Agreement between the Registrant and an executive officer of the Registrant (incorporated by reference to Exhibit 10.4 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
4.5	Shares Purchase Agreement by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, certain investors of Genetron Holdings Limited and other parties named therein dated July 2, 2019 (incorporated by reference to Exhibit 10.5 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
4.6	Share Repurchase Agreement by and between Genetron Holdings Limited and EASY BENEFIT INVESTMENT LIMITED dated October 1, 2019 (incorporated by reference to Exhibit 10.6 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).
4.7	Share Repurchase Agreement by and between Genetron Holdings Limited and Parkland Medtech Limited dated October 1, 2019 (incorporated by reference to Exhibit 10.7 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019).

4.8	Share Repurchase Agreement by and between Genetron Holdings Limited and CrowdBees Holdings Limited dated October 1, 2019 (incorporated by reference to Exhibit 10.8 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.9	Share Repurchase Agreement by and among Genetron Holdings Limited, FHP Holdings Limited, Hai Yan, Weiwu He, Genetron Voyage Holdings Limited and Genetron United Holdings Limited dated October 1, 2019 (incorporated by reference to Exhibit 10.9 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.10	Series C-2 Preferred Shares Purchase Agreement by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, and Vivo Capital Fund IX, L.P. dated October 1, 2019 (incorporated by reference to Exhibit 10.10 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.11	Amendment Agreement to Series C-2 Preferred Shares Purchase Agreement by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, and Vivo Capital Fund IX, L.P. dated November 19, 2019 (incorporated by reference to Exhibit 10.11 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.12	Series D Preferred Shares Purchase Agreement by and among Genetron Holdings Limited, Genetron Health (Hong Kong) Company Limited, Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd., Sizhen Wang, Hai Yan, Weiwu He, FHP Holdings Limited, certain investors of Genetron Holdings Limited and other parties named therein dated November 19, 2019 (incorporated by reference to Exhibit 10.12 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.13	Exclusive Business Cooperation Agreement dated July 2, 2019 by and between Genetron (Tianjin) Co., Ltd. and Genetron Health (Beijing) Co., Ltd. (incorporated by reference to Exhibit 10.13 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.14	Shareholder Voting Rights Entrustment Agreement dated July 30, 2019 by and among Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd. and the shareholders of Genetron Health (Beijing) Co., Ltd. (incorporated by reference to Exhibit 10.14 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.15	Equity Interest Pledge Agreement dated July 30, 2019 by and among Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd. and the shareholders of Genetron Health (Beijing) Co., Ltd. (incorporated by reference to Exhibit 10.15 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.16	Exclusive Option Agreement dated July 30, 2019 by and among Genetron (Tianjin) Co., Ltd., Genetron Health (Beijing) Co., Ltd. and the shareholders of Genetron Health (Beijing) Co., Ltd. (incorporated by reference to Exhibit 10.16 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.17	Spousal Consent granted by the spouse of Mr. Sizhen Wang dated July 30, 2019 (incorporated by reference to Exhibit 10.17 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.18	Spousal Consent granted by the spouse of Ms. Xiaoge Wang dated July 30, 2019 (incorporated by reference to Exhibit 10.18 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.19	Spousal Consent granted by the spouse of Ms. Shuyan Wei dated July 30, 2019 (incorporated by reference to Exhibit 10.19 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.20†	License and Supply Agreement dated January 1, 2018 by and between Life Technologies Corporation and Genetron Health (Beijing) Company, Ltd. (incorporated by reference to Exhibit 10.20 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.21†	Small Business Loan Agreement dated March 25, 2020 by and between Industrial and Commercial Bank of China Limited, Beijing Changping Sub-branch and Genetron Health (Beijing) Company, Ltd. (incorporated by reference to Exhibit 10.21 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.22†	RMB Working Capital Loan Agreement dated March 16, 2020 by and between China Construction Bank, Beijing Chaoyang Sub-branch and Genetron Health (Beijing) Company, Ltd. (incorporated by reference to Exhibit 10.22 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.23†	Credit Agreement by and between China Merchants Bank, Beijing Branch and Genetron Health (Beijing) Company, Ltd. (incorporated by reference to Exhibit 10.23 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)

4.24†	Technical Service Contract dated January 20, 2020 by and between Beijing Innocare Pharma Tech Co., Ltd. and Genetron Health (Beijing) Company, Ltd. (incorporated by reference to Exhibit 10.24 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.25†	Collaboration Agreement dated October 30, 2019 by and among iKang Guobin Healthcare Group, Inc., Chongqing Genetron Biotechnology Co., Ltd. and Chongqing Genetron Medical Laboratory Co., Ltd. (incorporated by reference to Exhibit 10.25 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
4.26†	Investment Agreement dated November 27, 2020 with respect to Genetron Health's Project of Precision Medicine Platform for Cancer Early Screening between Management Committee of Jiangsu Wuxi Huishan Economic Development Zone and Genetron Health (Hong Kong) Company Limited (incorporated by reference to Exhibit 4.26 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.27†	Strategic Cooperation Agreement dated January 6, 2021 with respect to Early Screening Product for Liver Cancer between Genetron Health (Beijing) Co., Ltd. and Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (incorporated by reference to Exhibit 4.27 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.28	Exclusive Business Cooperation Agreement dated December 7, 2020 by and between Genetron (Wuxi) Business Management Co., Ltd. and Genetron (Wuxi) Biotech Co., Ltd. (incorporated by reference to Exhibit 4.28 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.29	Shareholder Voting Rights Entrustment Agreement dated December 7, 2020 by and among Genetron (Wuxi) Business Management Co., Ltd., Genetron (Wuxi) Biotech Co., Ltd. and the shareholders of Genetron (Wuxi) Biotech Co., Ltd. (incorporated by reference to Exhibit 4.29 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.30	Equity Interest Pledge Agreement dated December 7, 2020 by and among Genetron (Wuxi) Business Management Co., Ltd., Genetron (Wuxi) Biotech Co., Ltd. and the shareholders of Genetron (Wuxi) Biotech Co., Ltd. (incorporated by reference to Exhibit 4.30 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.31	Exclusive Option Agreement dated December 7, 2020 by and among Genetron (Wuxi) Business Management Co., Ltd., Genetron (Wuxi) Biotech Co., Ltd. and the shareholders of Genetron (Wuxi) Biotech Co., Ltd. (incorporated by reference to Exhibit 4.31 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.32	Spousal Consent granted by the spouse of Mr. Sizhen Wang dated December 7, 2020 (incorporated by reference to Exhibit 4.32 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
4.33	Spousal Consent granted by the spouse of Mr. Yuchen Jiao dated December 7, 2020 (incorporated by reference to Exhibit 4.33 from our annual report on Form 20-F for the year ended December 31, 2021 (File No. 001-39328) filed with the SEC on April 9, 2021)
8.1*	Subsidiaries and the VIEs of the Registrant and Subsidiaries of the VIEs
11.1	Code of Business Conduct and Ethics of the Registrant (incorporated by reference to Exhibit 99.1 from our registration statement on Form F-1 (File No. 333-234805), as amended, initially filed publicly with the SEC on November 21, 2019)
12.1*	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1**	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2**	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of PricewaterhouseCoopers Zhong Tian LLP, Independent Registered Public Accounting Firm
15.2*	Consent of Walkers (Hong Kong)
15.3*	Consent of Shihui Partners
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 (embedded within the Inline XBRL document)

* Filed herewith

** Furnished herewith

† Certain material (indicated by three asterisks in brackets) has been omitted from this document because it is both (1) not material and (2) would be competitively harmful if publicly disclosed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing its annual report on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Date: April 29, 2022

Genetron Holdings Limited

By: /s/ Sizhen Wang

Name: Sizhen Wang

Title: Chief Executive Officer

GENETRON HOLDINGS LIMITED

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Genetron Holdings Limited

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Genetron Holdings Limited and its subsidiaries (the “Company”) as of December 31, 2021 and 2020, and the related consolidated statements of loss, comprehensive loss, changes in shareholders’ equity/(deficit) and cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the COSO.

Basis for Opinions

The Company’s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Annual Report on Internal Control over Financial Reporting appearing under Item 15. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company’s internal control over financial reporting based on our audits. 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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 consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company’s 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 generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

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 that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Loss allowance for Trade Receivables

As described in Notes 3.1(b) and 19 to the consolidated financial statements, as of December 31, 2021, the Company recorded total trade receivables of RMB336 million, net of an allowance for expected credit losses of RMB54 million. The allowance is management's estimate of expected credit losses on accounts receivable after considering quantitative and qualitative factors, applied under the simplified approach for trade receivables without a significant financing component by using a lifetime expected loss provision. Management makes periodic as well as individual assessments on the recoverability of trade receivables based on historical credit loss experience, as adjusted for forward looking information based on macroeconomic factors affecting the ability of the debtors to settle the receivables. Trade receivables from customers with known financial difficulties or with significant doubt on collection of receivables are assessed individually for a loss allowance. Management assesses remaining customers by grouping them based on shared credit risk characteristics. Management determines an expected loss rate for each group based on historical credit loss experience as well as current economic conditions and forecasts of future economic conditions in assessing the lifetime expected credit losses.

The principal considerations for our determination that performing procedures relating to the loss allowance for trade receivables is a critical audit matter are (i) the significant judgment by management in determining the expected credit losses as influenced by qualitative factors in particular, which led to a high level of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence obtained; and (ii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the loss allowance for trade receivables. These procedures also included, among others, the involvement of professionals with specialized skill and knowledge to assist in testing management's process for estimating the allowance for trade receivables. Testing management's process included (i) evaluating the appropriateness of the methodology and models; (ii) testing the completeness and accuracy of certain data used in the estimate; (iii) evaluating management's process to identify customers with known financial difficulties; and (iv) evaluating the reasonableness of significant assumptions and judgments made by management to estimate the allowance for credit losses, including the grouping of trade receivables based on certain credit risk characteristics as well as application of macroeconomic forecasts and certain qualitative adjustments to the allowance.

/s/ PricewaterhouseCoopers Zhong Tian LLP

Beijing, the People's Republic of China
April 29, 2022

We have served as the Company's auditor since 2018.

GENETRON HOLDINGS LIMITED
CONSOLIDATED STATEMENTS OF LOSS

	Notes	Year ended December 31,			
		2019 RMB'000	2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Revenue	6	323,425	424,485	531,950	83,475
Cost of revenue		(178,435)	(164,268)	(193,983)	(30,440)
Gross profit		<u>144,990</u>	<u>260,217</u>	<u>337,967</u>	<u>53,035</u>
Selling expenses		(253,558)	(246,959)	(343,161)	(53,850)
Administrative expenses		(117,169)	(126,318)	(227,001)	(35,622)
Research and development expenses		(91,697)	(148,999)	(253,950)	(39,850)
Net loss allowance for financial and contract assets		(2,733)	(14,843)	(37,032)	(5,811)
Other income and gains — net	9	13,297	8,526	5,329	836
Operating expenses		(451,860)	(528,593)	(855,815)	(134,297)
Operating loss		<u>(306,870)</u>	<u>(268,376)</u>	<u>(517,848)</u>	<u>(81,262)</u>
Finance income	10	2,483	28,330	20,501	3,217
Finance costs	10	(11,704)	(5,627)	(5,251)	(824)
Finance (costs)/income — net	10	<u>(9,221)</u>	<u>22,703</u>	<u>15,250</u>	<u>2,393</u>
Financial instruments with preferred rights					
— loss on fair value changes	30	(333,401)	(2,823,370)	—	—
— other loss		(26,542)	—	—	—
Loss before income tax		<u>(676,034)</u>	<u>(3,069,043)</u>	<u>(502,598)</u>	<u>(78,869)</u>
Income tax expense	11	—	—	—	—
Loss for the year		<u>(676,034)</u>	<u>(3,069,043)</u>	<u>(502,598)</u>	<u>(78,869)</u>
Loss attributable to:					
Owners of the Company		(676,034)	(3,069,043)	(496,238)	(77,871)
Non-controlling interests		—	—	(6,360)	(998)
Loss per share for loss attributable to owners of the Company		RMB	RMB	RMB	US\$
—Basic and diluted	12	<u>(5.41)</u>	<u>(10.18)</u>	<u>(1.08)</u>	<u>(0.17)</u>
Loss per ADS for loss attributable to owners of the Company					
—Basic and diluted	12		<u>(50.92)</u>	<u>(5.39)</u>	<u>(0.85)</u>

The accompanying notes are an integral part of these consolidated financial statements.

GENETRON HOLDINGS LIMITED

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Notes	Year ended December 31,			
		2019 RMB'000	2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Loss for the year		(676,034)	(3,069,043)	(502,598)	(78,869)
Other comprehensive (loss)/income					
<i>Items that may be reclassified to profit or loss</i>					
Exchange differences on currency translation of the Company's subsidiaries		(1,824)	10,325	11,252	1,766
<i>Items that will not be reclassified to profit or loss</i>					
Changes in fair value of financial instruments with preferred rights due to own credit risk	30	(17,299)	(72)	—	—
Exchange differences on currency translation of the Company		—	(161,467)	(50,610)	(7,942)
Other comprehensive loss for the year, net of tax		(19,123)	(151,214)	(39,358)	(6,176)
Total comprehensive loss for the year		(695,157)	(3,220,257)	(541,956)	(85,045)
Total comprehensive loss attributable to:					
Owners of the Company		(695,157)	(3,220,257)	(535,596)	(84,047)
Non-controlling interests		—	—	(6,360)	(998)
		(695,157)	(3,220,257)	(541,956)	(85,045)

The accompanying notes are an integral part of these consolidated financial statements.

GENETRON HOLDINGS LIMITED
CONSOLIDATED BALANCE SHEETS

	Notes	As of December 31,		
		2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
ASSETS				
Non-current assets				
Property, plant and equipment	13	76,891	110,285	17,306
Right-of-use assets	14(a)(i)	59,706	52,074	8,172
Intangible assets	15	12,265	20,695	3,247
Financial assets at fair value through profit or loss	21	19,609	49,780	7,812
Prepayments		15,362	37,610	5,902
Total non-current assets		183,833	270,444	42,439
Current assets				
Inventories	17	24,971	35,603	5,587
Contract assets	6	1,112	7,775	1,220
Other current assets	18	36,500	30,705	4,818
Trade receivables	19	164,592	282,113	44,270
Other receivables and prepayments	20	42,420	97,895	15,361
Amounts due from related parties	34(c)(i)	214	597	94
Financial assets at fair value through profit or loss	21	140,294	151,443	23,765
Derivative financial instruments	22	196	2,002	314
Cash and cash equivalents	23	1,375,766	639,042	100,280
Total current assets		1,786,065	1,247,175	195,709
Total assets		1,969,898	1,517,619	238,148
LIABILITIES				
Non-current liabilities				
Borrowings	28	5,493	—	—
Lease liabilities	14(a)(ii)	43,016	33,865	5,315
Other non-current liabilities	31	—	8,612	1,351
Total non-current liabilities		48,509	42,477	6,666
Current liabilities				
Trade payables		34,071	55,767	8,751
Contract liabilities	6	8,417	11,962	1,877
Other payables and accruals	29	111,164	157,232	24,673
Amounts due to related parties	34(c)(ii), 34(c)(iii)	24	3	1
Borrowings	28	58,583	19,554	3,068
Lease liabilities	14(a)(ii)	16,585	20,572	3,228
Total current liabilities		228,844	265,090	41,598
Total liabilities		277,353	307,567	48,264
Net assets		1,692,545	1,210,052	189,884
SHAREHOLDERS' EQUITY				
Equity attributable to owners of the Company				
Share capital	24	59	61	9
Share premium	24	6,657,562	6,711,234	1,053,139
Other reserves	26(b),(c),(d)	(24,701)	(69,091)	(10,841)
Accumulated losses		(4,940,375)	(5,436,613)	(853,123)
		1,692,545	1,205,591	189,184
Non-controlling interests		—	4,461	700
Total shareholders' equity		1,692,545	1,210,052	189,884

The accompanying notes are an integral part of these consolidated financial statements.

GENETRON HOLDINGS LIMITED
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY/(DEFICIT)

	Notes	Share capital (Note 24)	Treasury shares (Note 25)	Capital reserve (Note 26(a))	Share-based compensation reserve (Note 26(b))	Other reserve (Note 26(c))	Other comprehensive losses (Note 26(d))	Accumulated losses	Total shareholders' deficit
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at January 1, 2019		—	(8,363)	37,550	45,069	39,654	(10,013)	(1,167,943)	(1,064,046)
Comprehensive loss		—	—	—	—	—	—	(676,034)	(676,034)
Loss for the year		—	—	—	—	—	—	(676,034)	(676,034)
Exchange differences		—	—	—	—	—	(1,824)	—	(1,824)
Changes in fair value of financial instruments with preferred rights due to own credit risk	30	—	—	—	—	—	(17,299)	—	(17,299)
		—	—	—	—	—	(19,123)	(676,034)	(695,157)
Transactions with owners		—	—	—	—	—	—	—	—
Issuance of ordinary shares	24(iii)	18	—	—	—	—	—	—	18
Repurchase of ordinary shares	24(iv)	(1)	—	(35,174)	—	(22,264)	—	—	(57,439)
Re-designation of treasury shares		—	2,376	(2,376)	—	—	—	—	—
Vesting of restricted shares		—	2,409	—	(7,513)	7,513	—	—	2,409
Share-based compensations	27(d)	—	—	—	35,884	—	—	—	35,884
		17	4,785	(37,550)	28,371	(14,751)	—	—	(19,135)
Balance at December 31, 2019		17	(3,578)	—	73,440	24,903	(29,136)	(1,843,977)	(1,778,331)

GENETRON HOLDINGS LIMITED

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY/(DEFICIT) (CONTINUED)

	Notes	Share capital (Note 24)	Share premium (Note 24)	Treasury shares (Note 25)	Share-based compensation reserve (Note 26(b))	Other reserve (Note 26(c))	Other comprehensive losses (Note 26(d))	Accumulated losses	Total shareholders' (deficit)/equity
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at January 1, 2020		17	—	(3,578)	73,440	24,903	(29,136)	(1,843,977)	(1,778,331)
Comprehensive loss		—	—	—	—	—	—	—	—
Loss for the year		—	—	—	—	—	—	(3,069,043)	(3,069,043)
Exchange differences		—	—	—	—	—	(151,142)	—	(151,142)
Changes in fair value of financial instruments with preferred rights due to own credit risk	30	—	—	—	—	—	(72)	—	(72)
		—	—	—	—	—	(151,214)	(3,069,043)	(3,220,257)
Transfer of accumulated fair value change due to own credit risk of financial instruments with preferred rights upon conversion	30	—	—	—	—	—	27,355	(27,355)	—
Transactions with owners									
Issuance of ordinary shares upon IPO	24(vii)	11	1,657,782	—	—	—	—	—	1,657,793
Conversion of financial instruments with preferred rights into ordinary shares	24(viii)	31	4,999,780	—	—	—	—	—	4,999,811
Vesting of restricted shares		—	—	3,578	(8,283)	8,283	—	—	3,578
Share-based compensations	27(d)	—	—	—	29,951	—	—	—	29,951
		42	6,657,562	3,578	21,668	8,283	—	—	6,691,133
Balance at December 31, 2020		59	6,657,562	—	95,108	33,186	(152,995)	(4,940,375)	1,692,545

GENETRON HOLDINGS LIMITED
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY/(DEFICIT) (CONTINUED)

Notes	Equity attributable to owners of the Company						Non controlling interests	Total shareholders' equity
	Share capital (Note 24)	Share premium (Note 24)	Share-based compensation reserve (Note 26(b))	Other reserve (Note 26(c))	Other comprehensive losses (Note 26(d))	Accumulated losses		
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at January 1, 2021	59	6,657,562	95,108	33,186	(152,995)	(4,940,375)	—	1,692,545
Comprehensive loss								
Loss for the year	—	—	—	—	—	(496,238)	(6,360)	(502,598)
Exchange differences	—	—	—	—	(39,358)	—	—	(39,358)
	—	—	—	—	(39,358)	(496,238)	(6,360)	(541,956)
Transactions with owners								
Share-based compensations	27(d)	—	—	54,144	—	—	—	54,144
Exercise of awards	27(a)	2	53,672	(51,505)	—	—	—	2,169
Capital injection from non-controlling interests	31	—	—	—	—	—	10,821	10,821
Others	31	—	—	—	(7,671)	—	—	(7,671)
	2	53,672	2,639	(7,671)	—	—	10,821	59,463
Balance at December 31, 2021	61	6,711,234	97,747	25,515	(192,353)	(5,436,613)	4,461	1,210,052

The accompanying notes are an integral part of these consolidated financial statements.

GENETRON HOLDINGS LIMITED
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended December 31,			
		2019 RMB'000	2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Cash flows from operating activities					
Cash used in operations	32(a)	(196,957)	(300,897)	(524,144)	(82,250)
Net cash used in operating activities		(196,957)	(300,897)	(524,144)	(82,250)
Cash flows from investing activities					
Purchase of property, plant and equipment		(21,323)	(36,655)	(73,489)	(11,532)
Proceeds from sale of property, plant and equipment		4,940	—	—	—
Purchase of intangible assets		(4,261)	(13,371)	(12,404)	(1,946)
Purchase of wealth management products	3.3	(479,100)	(1,628,558)	(1,650,355)	(258,977)
Redemption of wealth management products		395,697	1,620,924	1,623,538	254,769
Investment income from wealth management products		723	4,476	4,991	783
Purchase of equity security	21(iii)	—	(13,721)	—	—
Purchase of other investments	21(i)	—	(19,000)	(28,895)	(4,534)
Purchase of derivative financial instruments		—	(68,078)	(415,346)	(65,177)
Settlement of derivative financial instruments		—	69,628	424,251	66,573
Loans to a related party	34(b)(iii)	(5,000)	—	—	—
Repayments of loans to a related party	34(b)(iii)	11,517	—	—	—
Placement of deposits with initial terms of over three months		—	—	(5,000)	(785)
Redemption of deposits with initial terms of over three months		—	—	5,000	785
Proceeds from sale of subsidiaries		—	—	2,000	314
Others		—	(294)	(10,566)	(1,657)
Net cash used in investing activities		(96,807)	(84,649)	(136,275)	(21,384)
Cash flows from financing activities					
Proceeds from issuance of ordinary shares	24(iii), (vii)	18	1,676,816	—	—
Proceeds from ADS depository	29	—	23,069	—	—
Proceeds from issuance of financial instruments with preferred rights	32(b), 30	456,568	70,026	—	—
Issuance costs of financial instruments with preferred rights		(6,303)	—	—	—
Repurchase of ordinary shares		(54,479)	(4,102)	—	—
Repurchase of financial instruments with preferred rights	32(b)	(43,279)	—	—	—
Proceeds from investors to the Company	32(b)	15,000	299,051	48,617	7,629
Repayments to investors from the Group	32(b)	—	(314,388)	(48,452)	(7,603)
Proceeds from exercise of awards		—	—	2,169	340
Capital injection from non-controlling interests	31	—	—	10,821	1,698
Proceeds from borrowings	32(b)	32,955	61,213	25,153	3,947
Repayments of borrowings	32(b)	(9,798)	(20,703)	(69,106)	(10,844)
Proceeds from loans from a related party	32(b), 34(b)(iii)	35,000	—	—	—
Repayments of loans from a related party	32(b), 34(b)(iii)	(35,000)	—	—	—
Principal elements of lease payments		(12,286)	(19,577)	(21,708)	(3,406)
Interests paid		(5,396)	(4,942)	(4,899)	(769)
Payments in relation to listing expenses		(1,269)	(21,691)	(1,000)	(157)
Others		—	(260)	—	—
Net cash generated from/(used in) financing activities		371,731	1,744,512	(58,405)	(9,165)
Net increase/(decrease) in cash and cash equivalents		77,967	1,358,966	(718,824)	(112,799)
Cash and cash equivalents at beginning of year		62,126	139,954	1,375,766	215,887
Exchange differences on cash and cash equivalents		(139)	(123,154)	(17,900)	(2,808)
Cash and cash equivalents at end of year	23	139,954	1,375,766	639,042	100,280

The accompanying notes are an integral part of these consolidated financial statements.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****1. General information, reorganization and basis of presentation****1.1 General information**

Genetron Holdings Limited (the “Company”) was incorporated in the Cayman Islands on April 9, 2018 as an exempted company with limited liability under the Companies Law (2020 Revision) of the Cayman Islands. The address of the Company’s registered office is at the office of Walkers Corporate Limited, Cayman Corporate Centre, 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands. The Company completed its initial public offering (“IPO”) on June 19, 2020 and the Company’s American Depositary Shares (“ADSs”) have been listed on the Nasdaq Global Market (“NASDAQ”) since then. Each ADS of the Company represents five ordinary shares.

The Company, its subsidiaries, its controlled structured entities (“variable interest entities” or “VIEs”) and its subsidiaries (“subsidiaries of VIEs”) are collectively referred to as the “Group”. The Group is principally engaged in precision oncology testing and development services (the “Listing Business”) in the People’s Republic of China (“PRC” or “China”).

1.2 Reorganization

Prior to the incorporation of the Company and the completion of the reorganization as described below, the Listing Business was carried out by Genetron Health (Beijing) Co., Ltd. (“Genetron Health”) and its subsidiaries (collectively the “Operating Companies”). Genetron Health was incorporated in the PRC on May 7, 2015 with Mr. Weiwu He, Mr. Sizhen Wang and Mr. Hai Yan considered as founding individuals (collectively the “Founders”).

Incorporation of overseas companies and their subsidiary in the PRC

For the purpose of preparation for the listing of the shares of the Company, the Group underwent a group reorganization (the “Reorganization”) to establish the Company as the ultimate holding company. The Reorganization mainly involved the following:

- (i) On April 9, 2018, the Company was incorporated in the Cayman Islands.
- (ii) On June 6, 2018, Genetron Health (Hong Kong) Company Limited (“Genetron HK”) was incorporated in Hong Kong (“HK”) as a direct wholly-owned subsidiary of the Company.
- (iii) On March 8, 2019, Genetron (Tianjin) Co., Ltd. (“Genetron TJ”) was established in the PRC with Genetron HK being its sole equity holder.
- (iv) Pursuant to a series of contractual arrangements in July 2019 (collectively referred to as the “Contractual Arrangements”) between Genetron TJ, Genetron Health and its respective equity holders, Genetron TJ is able to effectively control and receive substantially all the economic benefits of the business and operations of Genetron Health and its subsidiaries. Accordingly Genetron Health and its subsidiaries are treated as VIE and subsidiaries of VIE respectively which became controlled entities of the Company.

Upon completion of the Reorganization, each of the equity holders of Genetron Health became the shareholders of the Company with substantially the same rights and shareholding percentages in Genetron Health before and after the Reorganization, and the Company became the holding company of the companies now comprising the Group.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
1. General information, reorganization and basis of presentation (Continued)
1.2 Reorganization (Continued)

As of December 31, 2021, the Group has direct or indirect interests in the following principal subsidiaries, VIEs and subsidiaries of VIEs:

Company name	Place and date of incorporation	Registered/issued capital	Effective equity interest held	Principal activities
Directly held:				
Genetron HK	Hong Kong, June 6, 2018	HK\$10,000 (10,000 ordinary shares)	100 %	Investment holding
Genetron Health, Inc.	Delaware, United States of America August 23, 2019	US\$ 1 (1,000 ordinary shares)	100 %	Molecular diagnostic services
Indirectly held:				
Genetron TJ*	Tianjin, PRC March 8, 2019	RMB1,000,000,000	100 %	Biotechnology development and technical services
Shanghai Junran Bio-Technology Co., Ltd. *	Shanghai, PRC July 1, 2019	RMB500,000,000	100 %	Biotechnology development and technical services
Genetron (Wuxi) Business Management Co., Ltd. **	Wuxi, PRC December 3, 2020	US\$50,000,000	90 % (Note 31)	Investment holding
VIEs:				
Genetron Health	Beijing, PRC May 7, 2015	RMB57,438,800	100 %	Gene-related detection services
Genetron (Wuxi) Biotech Co., Ltd.	Wuxi, PRC October 14, 2020	RMB20,000,000	100 %	Gene-related detection services
Subsidiaries of VIEs:				
Shanghai Genetron Bio-Technology Co., Ltd.	Shanghai, PRC July 8, 2015	RMB20,000,000	100 %	Investment holding
Genetron Health (Chongqing) Co., Ltd.	Chongqing, PRC March 1, 2016	RMB20,000,000	100 %	Investment holding and IVD products sales
Beijing Genetron Biotechnology Co., Ltd.	Beijing, PRC March 11, 2016	RMB20,000,000	100 %	Investment holding
Guangzhou Genetron Bio-Technology Co., Ltd.	Guangzhou, PRC July 4, 2019	RMB10,000,000	100 %	Investment holding
Beijing Genetron Medical Laboratory Co., Ltd.	Beijing, PRC November 5, 2015	RMB12,000,000	100 %	Gene-related detection services
Shanghai Genetron Medical Laboratory Co., Ltd.	Shanghai, PRC December 14, 2015	RMB30,000,000	100 %	Gene-related detection services
Chongqing Genetron Medical Laboratory Co., Ltd.	Chongqing, PRC August 11, 2016	RMB20,000,000	100 %	Gene-related detection services
Guangzhou Genetron Medical Laboratory Co., Ltd.	Guangzhou, PRC July 8, 2019	RMB10,000,000	100 %	Gene-related detection services
Genetron Health Technologies, Inc.	Delaware, United States of America April 28, 2015	US\$ 10,000,000 (1,000 ordinary shares)	100 %	Research services

The place of incorporation is also their principal place of business and operations. All of them are limited liability companies.

* registered as wholly foreign owned enterprise under PRC law

** registered as non-wholly foreign owned enterprise under PRC law

Except for the VIEs and subsidiaries of VIEs which are controlled by the Company through Contractual Arrangements (Note 2.4.1(a)), other subsidiaries (including Genetron TJ and Genetron (Wuxi) Business Management Co., Ltd. which are collectively referred as “PRC Subsidiaries”) are controlled by the Company through direct or indirect equity ownerships.

1.3 Basis of presentation

Immediately prior to and after the Reorganization, the Listing Business was operated by Genetron Health and its subsidiaries. Pursuant to the Reorganization, the Listing Business was transferred to and held by the Company through the Operating Companies. The Company had not been involved in any other business prior to the Reorganization and did not meet the definition of a business. The Reorganization was merely a reorganization of the Listing Business with no change in management of such business. Accordingly, the Group resulting from the Reorganization was regarded as a recapitalization of the Listing Business under the Operating Companies for the purpose of these financial statements. The financial statements of the Group have been prepared on a consolidated basis as if the Reorganization had occurred historically and are presented using the carrying values of the assets, liabilities and operating results of the Listing Business under the Operating Companies.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies

This note provides a list of significant accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the periods presented, unless otherwise stated.

2.1 Basis of preparation

These consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (“IFRS”) issued by the International Accounting Standards Board (“IASB”). The financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through profit or loss, derivative financial instruments and financial instruments with preferred rights.

The financial statements were authorized for issue by the board of directors of the Company on April 29, 2022.

2.2 New standards, amendments to standards and interpretations adopted by the Group

The Group has applied the following for the first time for their annual reporting period commencing January 1, 2021:

- | | |
|--|--|
| • Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 | Interest Rate Benchmark Reform – Phase 2 |
| • Amendments to IFRS 16 | COVID-19-Related Rent Concessions |

The above amendments do not have any material impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods.

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.3 New standards, amendments to standards and interpretations not yet adopted

		Effective for annual periods beginning on or after
• Amendments to IAS 16	Property, Plant and Equipment: Proceeds before intended use	January 1, 2022
• Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract	January 1, 2022
• Amendments to IFRS 3	Reference to the Conceptual Framework	January 1, 2022
• Annual Improvements 2018 – 2020 cycle		January 1, 2022
• IFRS 17	Insurance Contracts	January 1, 2023
• Amendments to IAS 1	Classification of Liabilities as Current or Non-current	January 1, 2023
• Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	January 1, 2023
• Amendments to IAS 8	Definition of Accounting Estimates	January 1, 2023
• Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
• Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	To be determined

There are no new standards, amendments to existing standards or interpretations that are not yet effective and would be expected to have a material impact to the Group.

2.4 Principles of consolidation and equity accounting

2.4.1 Consolidation

A subsidiary is an entity (including VIE, as stated in Note 1 above) over which the Group has control. The Group controls an entity where the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Intra-group transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. When necessary, amounts reported by subsidiaries have been adjusted to conform with the Group's accounting policies.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.4 Principles of consolidation and equity accounting (Continued)

2.4.1 Consolidation (Continued)

Non-controlling interests in the results and equity of subsidiaries are shown separately in the consolidated statement of loss, statement of comprehensive loss, statement of changes in equity/(deficit) and balance sheet respectively.

(a) Subsidiaries controlled through Contractual Arrangements

The PRC Subsidiaries have entered into Contractual Arrangements, including the Shareholder Voting Rights Entrustment Agreements, Spousal Consent Letters, Equity Interest Pledge Agreements, Exclusive Business Cooperation Agreements and Exclusive Option Agreements, with the VIEs and their equity holders.

(i) Agreements that provide the Company with effective control over the VIEs

Shareholder Voting Rights Entrustment Agreements

Pursuant to the agreements among the PRC Subsidiaries, VIEs and the equity holders of VIEs, these equity holders irrevocably authorize the PRC Subsidiaries or any person(s) designated by the PRC Subsidiaries to act as his or her attorney-in-fact to exercise all of his or her rights as an equity holder of the VIEs, including, but not limited to, the right to call and attend shareholders' meetings, execute and deliver any and all written resolutions and meeting minutes as a shareholder, vote by itself or by proxy on any matters discussed on shareholders' meetings, sell, transfer, pledge or dispose of any or all of the shares, nominate, appoint or remove the directors, supervisors and senior management, and other shareholders rights conferred by the articles of association of the VIEs and the relevant laws and regulations.

Spousal Consent Letters

The spouse of each of Mr. Sizhen Wang and certain other individuals has signed spousal consent letters. Under the spousal consent letter, the spouse unconditionally and irrevocably waives any rights or entitlements whatsoever to such shares that may be granted to his/her pursuant to applicable laws and undertakes not to make any assertion of rights to such shares. The spouse agrees and undertakes that he/she will take all necessary actions to ensure the proper performance of the Contractual Arrangements, and will be bound by the Contractual Arrangements in case he/she obtains any equity of the VIEs due to any reason.

Equity Interest Pledge Agreements

Pursuant to the agreements among the PRC Subsidiaries and the equity holders of VIEs, the equity holders of VIEs have pledged 100% equity interest in the VIEs in favor of the PRC Subsidiaries to guarantee the performance by the VIEs and their equity holders of their obligations under the Exclusive Business Cooperation Agreements, the Exclusive Option Agreements and any other agreement to be executed among the PRC Subsidiaries, VIEs and the equity holders from time to time. If the VIEs or their equity holders breach their contractual obligations under the agreements, the PRC Subsidiaries, as pledgees, will have the right to dispose of the pledged shares entirely or partially. The equity holders of the VIEs also agreed, without the PRC Subsidiaries' prior written consents, not to transfer the pledged shares, establish or permit the existence of any security interest or other encumbrance on the pledged shares, or dispose of the pledged shares by any other means, except by the performance of the Exclusive Option Agreements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.4 Principles of consolidation and equity accounting (Continued)

2.4.1 Consolidation (Continued)

- (a) Subsidiaries controlled through Contractual Arrangements (Continued)
- (ii) Agreements that allow the Company to receive economic benefits from the VIEs

Exclusive Business Cooperation Agreements

Pursuant to the agreements between the PRC Subsidiaries and VIEs, the PRC Subsidiaries or their designated entities affiliated have the exclusive right to provide the VIEs with technical support, business support and consulting services in return for fees equal to 100% of the consolidated net profits of the VIEs. Without the PRC Subsidiaries' prior written consents, the VIEs shall not, directly and indirectly, obtain the same or similar services as provided under the agreements from any third party, or enter into any similar agreement with any third party. The PRC Subsidiaries have the right to determine the service fee charged to the VIEs under the agreements by considering, among other things, the complexity of the services, the time spent by employees of the PRC Subsidiaries to provide the services, contents and commercial value of the service provided, as well as the benchmark price of similar services in the market. The PRC Subsidiaries will have the exclusive ownership of all intellectual property rights developed by performance of the agreements.

- (iii) Agreements that provide the Company with the option to purchase the equity interests in the VIEs

Exclusive Option Agreements

Pursuant to the agreements among the PRC Subsidiaries, VIEs and their equity holders, the equity holders of VIEs irrevocably granted the PRC Subsidiaries or any third party designated by the PRC Subsidiaries an exclusive option to purchase all or part of their equity interests in the VIEs at the lowest price permitted by applicable PRC laws. Those equity holders further undertake that they will neither allow the encumbrance of any security interest in the VIEs, except for the pledge created pursuant to the Equity Interest Pledge Agreements, nor transfer, mortgage or otherwise dispose of their legal or beneficial interests in the VIEs without the prior written consents of the PRC Subsidiaries, and will cause the shareholders' meeting and/or the board of directors and/or the executive directors of the VIEs not to approve such proposal.

In the opinion of the Company's management, the Contractual Arrangements enable the PRC Subsidiaries and the Group to:

- exercise effective control over the VIEs;
- receive substantially all of the economic benefits of the VIEs; and
- have an exclusive option to purchase all or part of the equity interest in and/or assets of the VIEs when and to the extent permitted by laws.

The Group does not have any equity interests in the VIEs. As a result of the Contractual Arrangements, the Group has rights to variable returns from its involvement in the VIEs and has the ability to affect those returns through its power over the VIEs, and is thereby considered to control the VIEs. Consequently, the Company regards the VIEs as indirect subsidiaries under IFRS. The Group has included the financial position and results of the VIEs and their subsidiaries in the consolidated financial statements. There is currently no contractual arrangement that requires the Company to provide additional financial support to the VIEs.

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.4 Principles of consolidation and equity accounting (Continued)

2.4.1 Consolidation (Continued)

(b) Risks in relation to VIEs and subsidiaries of VIEs

After completion of the Reorganization, a significant part of the Group's business is conducted through VIEs and subsidiaries of VIEs. The Company becomes the primary beneficiary through the Contractual Arrangements. In the opinion of management, the ownership structure of the VIEs is not in violation of any existing PRC law or regulation in any material respect; and the Contractual Arrangements are in compliance with PRC laws and are valid, legally binding and enforceable. However, uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules could limit the Company's ability to enforce the Contractual Arrangements.

In March 2019, the National People's Congress of the PRC adopted the PRC Foreign Investment Law, which became effective on January 1, 2020. Among other things, the PRC Foreign Investment Law defines the "foreign investment" as investment activities in China by foreign investors in a direct or indirect manner, including those circumstances explicitly listed above as establishing new projects or foreign invested enterprises or acquiring shares of enterprises in China, and other approaches of investment as stipulated by laws, administrative regulations or otherwise regulated by the State Council. The PRC Foreign Investment Law leaves uncertainty as to whether foreign investors' controlling PRC onshore variable interest entities via contractual arrangements will be recognized as "foreign investment" and thus be subject to the restrictions/prohibitions on foreign investments.

Current PRC laws and regulations impose certain restrictions or prohibitions on foreign ownership of companies that engage in the development and application of technologies for diagnosis and treatment of human stem cells and genes ("genomics business"), to which the precision oncology service of the Group relates. Pursuant to the Special Administrative Measures (Negative List) issued by the National Development and Reform Committee and Ministry of Commerce of the PRC on June 30, 2019, which came into force on July 30, 2019, certain industries are specifically prohibited for foreign investment, including genomics business. To comply with PRC laws and regulations, the Group conducts related business in China through VIEs.

If the corporate structure of the Group or the Contractual Arrangements between the VIEs and subsidiaries of VIEs and their respective equity holders were found to be in violation of the current or future PRC laws and regulations, the PRC government could:

- revoke the Group's business and operating licenses;
- require the Group to discontinue or restrict its operations;
- restrict the Group's right to collect revenues;
- require the Group to restructure the operations, re-apply for the necessary licenses or relocate its businesses, staff and assets;
- impose additional conditions or requirements with which the Group may not be able to comply; or
- take other regulatory or enforcement actions against the Group that could be harmful to the Group's business.

The Company's ability to conduct its business may be negatively affected if the PRC government carries out any of the aforementioned actions. As a result, the Company may not be able to consolidate its VIEs and subsidiaries of VIEs in its consolidated financial statements as it may lose the ability to exert effective control over them or it may lose the ability to receive economic benefits from them.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
2. Summary of significant accounting policies (Continued)
2.4 Principles of consolidation and equity accounting (Continued)
2.4.1 Consolidation (Continued)
(b) Risks in relation to VIEs and subsidiaries of VIEs (Continued)

Summarized condensed financial information of the Group's VIEs and subsidiaries of VIEs:

	As of December 31,		
	2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Non-current assets	169,152	189,393	29,720
Current assets	335,772	556,527	87,331
Total assets	504,924	745,920	117,051
Non-current liabilities	780,519	1,402,408	220,068
Current liabilities	229,062	267,888	42,038
Total liabilities	1,009,581	1,670,296	262,106

	Year ended December 31,			
	2019 RMB'000	2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Revenue	323,425	424,485	534,111	83,814
Loss for the year	(406,239)	(236,102)	(425,411)	(66,756)
Net cash used in operating activities	(192,068)	(196,594)	(405,910)	(63,696)
Net cash used in investing activities	(96,807)	(9,223)	(52,699)	(8,270)
Net cash generated from financing activities	238,061	200,767	529,270	83,054
Net (decrease)/increase in cash and cash equivalents	(50,814)	(5,050)	70,661	11,088

The above includes intercompany balances and transactions which have been eliminated on the Company's consolidated financial statements.

As of December 31, 2020 and 2021, the total assets of the Group's VIEs and subsidiaries of VIEs mainly include cash and cash equivalents, financial assets at fair value through profit or loss, trade receivables, other receivables and prepayments, inventories, property, plant and equipment as well as right-of-use assets; and the total liabilities of the Group's VIEs and subsidiaries of VIEs mainly include trade payables, amounts due to Group companies, other payables and accruals, borrowings as well as lease liabilities. Amounts due to Group companies are RMB767,789,000 and RMB1,449,810,000 as of December 31, 2020 and 2021 respectively.

The PRC Subsidiaries did not charge any service fees from the VIEs and subsidiaries of VIEs during the reported periods. During 2019, 2020 and 2021, loans advanced from Group companies to the VIEs totalled RMB232,586,000, RMB499,424,000 and RMB928,600,000; and repayments of such loans totalled nil, nil and RMB282,480,000, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.4 Principles of consolidation and equity accounting (Continued)****2.4.1 Consolidation (Continued)****(c) Business combination**

The Group applies the acquisition method to account for business combinations except for business combinations under common control. For acquisition method, the consideration transferred for the acquisition of a subsidiary is the fair values of the assets transferred, the liabilities incurred to the former owners of the acquiree and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date.

The Group recognizes any non-controlling interest in the acquiree on an acquisition-by-acquisition basis, either at fair value or at the non-controlling interest's proportionate share of the recognized amounts of acquiree's identifiable net assets.

Acquisition-related costs are expensed as incurred.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition-date fair value of any previous equity interest in the acquiree over the fair value of the identifiable net assets acquired is recorded as goodwill. If the total of consideration transferred, non-controlling interest recognized and previously held interest measured is less than the fair value of the net assets of the subsidiary acquired in the case of a bargain purchase, the difference is recognized directly in profit or loss.

There is no business combination during the reported periods.

2.4.2 Associates, joint arrangements and equity method**(a) Associates**

Associates are all entities over which the Group has significant influence but not control or joint control. This is generally the case where the Group holds between 20% and 50% of the voting rights. The Group's investments in associates in the form of redeemable instruments are financial assets designated at fair value through profit or loss. Investments in associates in the form of ordinary shares with significant influence are accounted for using the equity method of accounting (Note 2.4.2(c)), after initially being recognized at cost.

(b) Joint arrangements

Investments in joint arrangements are classified as either joint operations or joint ventures. The classification depends on the contractual rights and obligations of each investor, rather than the legal structure of the joint arrangement.

The Group recognizes its direct right to the assets, liabilities, revenues and expenses of joint operations and its share of any jointly held or incurred assets, liabilities, revenues and expenses. These are incorporated in the financial information under the appropriate headings.

Interests in joint ventures are accounted for using the equity method (Note 2.4.2(c)), after initially being recognized at cost.

The Group has no joint arrangements during the reported periods.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.4 Principles of consolidation and equity accounting (Continued)****2.4.2 Associates, joint arrangements and equity method (Continued)****(c) Equity method**

Under the equity method of accounting, the investments are initially recognized at cost and adjusted thereafter to recognize the Group's share of the post-acquisition profits or losses of the investee in profit or loss, and the Group's share of movements in other comprehensive income of the investee in other comprehensive income. Dividends received or receivable from associates and joint ventures are recognized as a reduction in the carrying amount of the investment.

Where the Group's share of losses in an equity-accounted investment equals or exceeds its interest in the entity, including any other unsecured long-term receivables, the Group does not recognize further losses, unless it has incurred obligations or made payments on behalf of the entity.

Unrealized gains on transactions between the Group and its associates and joint ventures are eliminated to the extent of the Group's interest in these entities. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of equity-accounted investees have been changed where necessary to ensure consistency with the policies adopted by the Group.

The carrying amount of equity-accounted investments is tested for impairment in accordance with the policy described in Note 2.8.

2.4.3 Parent company only financial information

Until December 31, 2020, interests in subsidiaries are accounted for at cost less impairment. Cost includes direct attributable costs of investment. The results of subsidiaries are accounted for by the parent company on the basis of dividend received and receivable.

From January 1, 2021, the parent company has changed from cost method to equity method to account for its interests in subsidiaries to provide more relevant information on its financial position and financial performance. This change is applied retrospectively for all the years presented with the net loss of parent company only for each of the years ended December 31, 2019 and 2020 increased by RMB416,121,000 and RMB225,796,000 respectively; and the shareholders' deficit and shareholders' equity of parent company only as of December 31, 2019 and 2020 increased and decreased by RMB 1,615,580,000 and RMB2,131,052,000 respectively as a result.

Parent company only condensed financial information is disclosed in Note 35.

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.5 Foreign currency translation

(a) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ("functional currency"). The financial statements are presented in Renminbi ("RMB"), which is the functional currency of most entities within the Group, unless otherwise stated.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions, and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates, are generally recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings and cash and cash equivalents are presented in the statements of loss within finance income/(costs). All other foreign exchange gains and losses are presented in the statements of loss within other income and gains/(losses).

(c) Group companies

The results and financial position of all the Group entities that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each statement of comprehensive income/(loss) are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions); and
- all resulting currency translation differences are recognized in other comprehensive income/(loss).

(d) Convenience translation

Translations of the consolidated balance sheets, the consolidated statements of loss, comprehensive loss and cash flows from RMB into United States dollars ("US\$") as of and for the year ended December 31, 2021 are solely for the convenience of the readers and calculated at the rate of US\$1.00=RMB6.3726 representing the exchange rate as of December 30, 2021 set forth in the H.10 statistical release of the U.S. Federal Reserve Board. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into US\$ at that rate, or at any other rate, on December 30, 2021.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****2. Summary of significant accounting policies (Continued)****2.6 Property, plant and equipment**

Property, plant and equipment are stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost, net of their residual values, over their estimated useful lives or, in the case of leasehold improvements and certain leased plant and equipment, the shorter lease term as follows:

Instruments and equipment	3-5 years
Office equipment and furniture	3-5 years
Transporting equipment	4 years
Leasehold improvements	shorter of lease period or 3-7 years

The assets' residual values and useful lives are reviewed and adjusted if appropriate at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (Note 2.8).

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized within other income and gains/(losses) in the statements of loss.

2.7 Intangible assets**(a) Software**

Acquired software licenses are capitalized on the basis of the costs incurred to acquire and bring the specific software into usage. These costs are amortized using the straight-line method over their estimated useful lives of about 5-10 years. Costs associated with maintaining software programs are recognized as expense as incurred.

(b) Patented technologies

Separately acquired patent technologies are shown at historical cost. Patent technologies acquired in a business combination are recognized at fair value at the acquisition date. They have finite useful lives based on the terms of patents and are subsequently carried at cost less accumulated amortization and impairment losses.

(c) Other intangible assets

Other intangible assets were recognized upon a historical acquisition of a subsidiary. It is amortized using the straight-line method over the estimated useful life of the intangible assets of 4 years.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.7 Intangible assets (Continued)****(d) Research and development**

The Group incurs costs and efforts on research and development activities. Research expenditures are charged to the profit or loss as an expense in the period the expenditure is incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed service or product and all the following can be demonstrated:

- the technical feasibility to complete the development project so that it will be available for use or sale;
- the intention to complete the development project to use or sell the service or product;
- the ability to use or sell the service or product;
- the manner in which the development project will generate probable future economic benefits for the Group;
- the availability of adequate technical, financial and other resources to complete the development project and use or sell the service or product; and
- the expenditure attributable to the asset during its development can be reliably measured.

The development cost of an internally generated intangible asset is the sum of the expenditure incurred from the date the asset meets the recognition criteria above to the date when it is available for use. The development costs capitalized in connection with the intangible asset include costs of materials and services used or consumed, employee costs incurred in the creation of the asset and an appropriate portion of relevant overheads.

Capitalized development costs are amortized using the straight-line method over the life of the related service or product. Amortization shall begin when the asset is available for use.

Development expenditures not satisfying the above criteria are recognized in the profit or loss as incurred.

2.8 Impairment of non-financial assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. No goodwill or intangible assets with an indefinite useful life were recognized during the reported periods.

Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.9 Financial assets

(a) Classification

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income (“OCI”) or through profit or loss), and
- those to be measured at amortized cost.

The classification depends on the entity’s business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through OCI (“FVOCI”).

The Group reclassifies debt investments when and only when its business model for managing those assets changes.

(b) Recognition and derecognition

Regular way purchases and sales of financial assets are recognized on trade date, being the date on which the Group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

(c) Measurement

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (“FVPL”), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

(i) Debt instruments

Subsequent measurement of debt instruments depends on the Group’s business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Group classifies its debt instruments:

- Amortized cost: Assets that are held for collection of contractual cash flows, where those cash flows represent solely payments of principal and interest, are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognized directly in profit or loss and presented in other income and gains/(losses). Impairment losses are presented as separate line item in the statements of loss.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****2. Summary of significant accounting policies (Continued)****2.9 Financial assets (Continued)****(c) Measurement (Continued)****(i) Debt instruments (Continued)**

- FVOCI: Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognized in profit or loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in OCI is reclassified from equity to profit or loss and recognized in other income and gains/(losses). Interest income from these financial assets is included in finance income using the effective interest rate method. Impairment losses are presented as separate line item in the statements of loss.
- FVPL: Assets that do not meet the criteria for amortized cost or FVOCI are measured at FVPL. A gain or loss on a debt investment that is subsequently measured at FVPL is recognized in profit or loss and presented within other income and gains/(losses) in the period in which it arises.

(ii) Equity instruments

The Group subsequently measures all equity investments at fair value. Where the Group's management has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income and gains when the Group's right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognized in other income and gains/(losses) in the statements of loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

(d) Impairment

The Group assesses on a forward-looking basis the expected credit losses associated with its debt instruments carried at amortized cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For trade receivables and contract assets with no significant financing component, the Group applies the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables.

2.10 Derivatives

Derivatives are initially recognized at fair value on the date a derivative contract is entered into, and they are subsequently remeasured to their fair value at the end of each reporting period. The accounting for subsequent changes in fair value depends on whether the derivative is designated as a hedging instrument and, if so, the nature of the item being hedged. Trading derivatives are classified as a current asset or liability.

The Group's derivative instruments do not qualify for hedge accounting. Changes in the fair value of any derivative instrument that does not qualify for hedge accounting are recognized immediately in profit or loss and are included in other income and gains/(losses).

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****2. Summary of significant accounting policies (Continued)****2.11 Inventories**

Raw materials, work in progress and finished goods are stated at the lower of cost and net realizable value. The cost of finished goods and work in progress comprises raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity). Costs of purchased inventories are determined after deducting rebates and discounts. Cost is determined using the weighted average method. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

2.12 Trade and other receivables

Trade receivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business. If collection of trade and other receivables is expected in one year or less (or in the normal operating cycle of the business if longer), they are classified as current assets. If not, they are presented as non-current assets.

Trade and other receivables are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value. The Group holds the trade and other receivables with the objective of collecting the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method. See Note 3.1(b) for a description of the Group's impairment policies.

2.13 Cash and cash equivalents

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the balance sheets.

2.14 Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or awards are shown in equity as a deduction, net of tax, from the proceeds.

2.15 Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the end of financial year which are unpaid. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method. Trade payables are unsecured with usual payment terms of 30 days.

2.16 Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method.

Borrowings are removed from the balance sheets when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognized in profit or loss as finance costs.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.17 Borrowing costs**

General and specific borrowing costs that are directly attributable to the acquisition, construction or production of a qualifying asset are capitalized during the period of time that is required to complete and prepare the asset for its intended use or sale. Qualifying assets are assets that necessarily take a substantial period of time to get ready for their intended use or sale.

Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs eligible for capitalization.

Other borrowing costs are expensed in the period in which they are incurred.

2.18 Financial instruments with preferred rights

Financial instruments with preferred rights issued by the Group are convertible into ordinary shares upon the closing of a qualified IPO or at the option of the holders and redeemable upon occurrence of certain future events.

The Group designates the financial instruments with preferred rights as financial liabilities at fair value through profit or loss. They are initially recognized at fair value. Any directly attributable transaction costs are expensed in the consolidated statements of loss.

Subsequent to initial recognition, the amount of change in the fair value of the financial instruments with preferred rights that is attributable to changes in the credit risk of that liability shall be presented in OCI with the remaining changes in fair value recognized in profit or loss.

As of December 31, 2020 and 2021, all financial instruments with preferred rights were converted into ordinary shares upon completion of IPO on June 19, 2020.

2.19 Current and deferred income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income, based on the applicable income tax rate for each jurisdiction, adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

(a) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions, where appropriate, on the basis of amounts expected to be paid to the tax authorities.

Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.19 Current and deferred income tax (Continued)****(b) Deferred income tax**

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in foreign operations where the Group is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset where there is a legally enforceable right to offset current tax assets and liabilities and where the deferred tax balances relate to the same taxation authority.

2.20 Employee benefits**(a) Short-term obligations**

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the balance sheets.

(b) Pension obligations

The Group incorporated in the PRC contributes based on certain percentage of the salaries of the employees to a defined contribution retirement benefit plan organized by relevant government authorities in the PRC on a monthly basis. The government authorities undertake to assume the retirement benefit obligations payable to all existing and further retired employees under these plans and the Group has no further obligation for post-retirement benefits beyond the contributions made. Contributions to these plans are expensed as incurred. Assets of the plans are held and managed by government authorities and are separate from those of the Group.

(c) Housing funds and medical insurance

The PRC employees of the Group are entitled to participate in various government-supervised housing funds and medical insurance. The Group contributes on a monthly basis to these funds based on certain percentage of the salaries of the employees, subject to certain ceiling. The Group's liability in respect of these funds is limited to the contribution payable in each period and recognized as employee benefit expense when they are due.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.21 Share-based payment**

Share-based compensation benefits (including restricted ordinary shares, share options and restricted share units (“RSU”), collectively the “awards”) are provided to employees and consultants via the Share Incentive Plan and Share Incentive Scheme with information being set out in Note 27(a).

The fair value of awards granted is recognized as an employee benefits expense with a corresponding increase in equity. The total amount to be expensed is determined by reference to the fair value of the awards granted:

- including any market performance conditions (e.g. the entity’s share price)
- excluding the impact of any service and non-market performance vesting conditions (e.g. profitability, sales growth targets and remaining an employee of the entity over a specified time period), and
- including the impact of any non-vesting conditions (e.g. the requirement for employees to save or hold shares for a specific period of time).

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each period, the Group revises its estimates of the vesting period and the number of awards that are expected to vest based on the service and non- market performance vesting conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity. The Group applies prospective treatment in respect of accounting for modifications of equity-settled awards that reduce the vesting period, if any.

2.22 Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable.

Revenues are recognized when, or as, the control of the goods or services is transferred to the customer. Depending on the terms of the contract and the laws applicable, control of the goods and services may be transferred over time or at a point in time. Control of the goods and services is transferred over time if the Group’s performance:

- provides all of the benefits received and consumed simultaneously by the customer;
- creates and enhances an asset that the customer controls as the Group performs; or
- does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date (collectively referred as “Over Time Conditions”).

If control of the goods and services transfers over time, revenue is recognized over the period of the contract by reference to the progress towards complete satisfaction of that performance obligation. Otherwise, revenue is recognized at a point in time when the customer obtains control of the goods and services.

The progress towards complete satisfaction of performance obligation, depending on the nature of the goods and services to be transferred, is measured based on one of the following methods that best depicts the Group’s performance in satisfying the performance obligation:

- direct measurements of the value of individual services transferred by the Group to the customer; or
- the Group’s efforts or inputs to the satisfaction of the performance obligation.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)

2.22 Revenue recognition (Continued)

When determining the transaction price to be allocated to different performance obligations, the Group first determines the fees that the Group entitles in the contract period. The Group includes in the transaction price some or all of an amount of variable considerations only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

If contracts involve the sale of multiple goods, goods followed by related services, or multiple services, the transaction price will be allocated to each performance obligation based on their relative stand-alone selling prices. If the stand-alone selling prices are not directly observable, they are estimated based on expected cost plus a margin or adjusted market assessment approach, depending on the availability of observable information.

The Group has two main revenue streams which are (a) diagnosis and monitoring; and (b) development services.

(a) Diagnosis and monitoring

Diagnosis and monitoring as well as early screening (collectively “precision oncology testing”) refer to those performed in the form of laboratory developed tests (“LDT”) services and in-vitro diagnostic (“IVD”) products. The service period of each testing is generally around 1 to 2 weeks. Customers of the Group include individuals and enterprises, distributors and hospitals. Revenue is recognized when the performance obligations are satisfied.

The testing is designed for each individual. The Group recognizes revenue over time when it has an enforceable right to payment for performance completed to date. The progress of precision oncology recognized over time is measured based on the Group’s input to the satisfaction of related performance obligation.

Revenue from the testing is recognized at a point in time when the Over Time Conditions are not met. For those arrangements, the Group recognizes revenue when the report is delivered.

Revenue from sales of IVD products is recognized when control of IVD products is transferred upon that hospitals and institutional customers have received and accepted the products.

(b) Development services

Revenue from development services refers to the research services and sequencing services. Research services are recognized over time when it has an enforceable right to payment for performance completed to date. The progress of research services is measured based on the Group’s inputs or outputs to the satisfaction of related performance obligation of research services. Sequencing services are recognized at a point in time when the Over Time Conditions are not met. For those arrangements, the Group recognizes revenue when the report is delivered.

(c) Principal-agent consideration

The Group performs the underlying precision oncology testing and development services. When another party is involved in providing the service to an end customer, the Group will determine whether the other party is the principal or the agent to the end customer. The Group reports the revenue on a gross or net basis depending on whether the other party is acting as a principal or an agent to the end customer in a transaction. This determination is based on an evaluation of various factors including but not limited to whether the other party (i) is the primary obligor in the arrangement; (ii) has latitude in establishing the selling price; and (iii) has inventory risk before the specified good or service is transferred to a customer or after transfer of control to the customer. When the other party is acting as a principal to the end customer, the Group considers the other party as its customer and records the net amount from the other party as revenue. When the other party is acting as an agent, the Group considers the end customer as its customer and records the gross amount from the end customer as revenue.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****2. Summary of significant accounting policies (Continued)****2.22 Revenue recognition (Continued)****(d) Financing components**

The Group does not expect to have any contracts where the period between the transfer of the promised goods or services to the customer and payment by the customer exceeding one year. As a consequence, the Group does not adjust any of the transaction prices for the time value of money.

(e) Contract assets and liabilities

When either party to a contract has performed, the Group presents the contracts in balance sheets as a contract asset or a contract liability, depending on the relationship between the Group's performance and customers' payment.

A contract asset is the Group's right to consideration in exchange for goods or services which the Group has transferred to customers. Contract asset is subject to the impairment of expected credit losses model under IFRS 9.

Incremental costs incurred to obtain a contract, if recoverable, are capitalized and presented as contract assets and subsequently amortized when the related revenue is recognized. For those costs with amortization periods of less than 1 year, they are expensed as incurred.

If a customer pays consideration or the Group has a right to an amount of consideration that is unconditional, before the Group transfers a good or service to the customer, the Group presents the contract as a contract liability when the payment is made or the receivable is recorded (whichever is earlier). A contract liability is the Group's obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer.

A receivable is recorded when the Group has an unconditional right to consideration. A right to consideration is unconditional if only the passage of time is required before payment of that consideration is due.

2.23 Cost of revenue

Cost of revenue is principally related to costs of services. Costs of services primarily consist of costs of raw materials consumed during the process of revenue-generating services, salaries and benefits for production personnel (including related share-based compensations), rental and depreciation expenses as well as maintenance of equipment, and other related costs of operations.

2.24 Selling expenses

Selling expenses primarily include promotion and marketing expenses as well as employee benefits related to sales personnel including share-based compensations.

2.25 Administrative expenses

Administrative expenses primarily include payroll and related expenses for employees involved in general corporate functions including finance, legal and human resources, rental and depreciation expenses related to facilities and equipment used by these functions, professional service expenses and other general corporate related expenses.

2.26 Research and development expenses

As stated in Note 2.7(d), all expenditure related to research and development is recorded in expenses when it could not meet the criteria of capitalization.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of significant accounting policies (Continued)**2.27 Interest income**

Interest income is recognized using the effective interest method.

2.28 Government grants

Grants from the government are recognized at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions.

Where the grants relates to an expense item, it is recognized as income on a systematic basis over the period that the costs, which it is intended to compensate, are expensed. Where the grants relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset on straight-line basis or deducted from the carrying amount of the asset and released to the profit or loss by way of a reduced depreciation charge.

2.29 Leases

The Group leases various properties and office equipment. Rental contracts are typically made for fixed periods of approximately 2 to 7 years but may have extension options as described below.

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group.

Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. However, for leases of real estate for which the Group is a lessee, it has elected not to separate lease and non- lease components and instead accounts for these as a single lease component.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable,
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as at the commencement date,
- amounts expected to be payable by the Group under residual value guarantees,
- the exercise price of a purchase option if the Group is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that termination option.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****2. Summary of significant accounting policies (Continued)****2.29 Leases (Continued)**

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, the lessee's incremental borrowing rate is used, being the rate that the lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability,
- any lease payments made at or before the commencement date less any lease incentives received,
- any initial direct costs, and
- restoration costs.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less.

In the statement of cash flows, cash flows related to leases are classified as the followings:

- cash payments for the principal and interest elements of the lease liabilities are classified within financing activities;
- short-term lease payments, payments for leases of low-value assets and variable lease payments not included in the measurement of the lease liabilities are classified within operating activities.

2.30 Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ("CODM"). The CODM has been identified as the Chief Executive Officer ("CEO") of the Company who makes strategic decisions, monitors daily operation of the Group, allocates resources and assesses performance of the operating segments.

2.31 Loss per share**(a) Basic loss per share**

Basic loss per share is calculated by dividing:

- the loss attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****2. Summary of significant accounting policies (Continued)****2.31 Loss per share (Continued)****(a) Basic loss per share (Continued)**

- by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year and excluding treasury shares

(b) Diluted loss per share

Diluted loss per share adjusts the figures used in the determination of basic loss per share to take into account:

- the after-income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and
- the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares.

3. Financial risk management**3.1 Financial risk factors**

The Group's activities expose it to a variety of financial risks: market risk (including interest rate risk and exchange risk), credit risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Risk management is carried out by the senior management of the Group.

(a) Market risk**(i) Interest rate risk**

The Group's interest rate risk primarily arises from wealth management products (Note 21(ii)), bank deposits (Note 23), borrowings (Note 28) and loans to/from related parties (Note 34(b) (iii)). Those carried at variable rates expose the Group to cash flow interest rate risk whereas those at fixed rates expose the Group to fair value interest rate risk. Interest amounts continue to be insignificant during the reported periods.

(ii) Exchange risk

The Group is exposed to exchange risk arising from foreign currency exposures, primarily with respect to US\$. Foreign exchange risk arises when future commercial transactions or recognized assets or liabilities are denominated in a currency that is not the functional currency of the Group entity. The Group's net result is not significantly impacted since transactions, assets and liabilities of each Group entity are mostly denominated in the functional currency of the respective entity.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
3. Financial risk management (Continued)
3.1 Financial risk factors (Continued)
(b) Credit risk

Credit risk primarily arises from wealth management products, cash and cash equivalents, trade and other receivables, amounts due from related parties and contract assets. The maximum exposure to credit risk is represented by the carrying amount of each financial asset in the balance sheets.

The credit risk of wealth management products and cash and cash equivalents is limited because the counterparties are mainly state-owned or reputable commercial institutions located in the PRC and Hong Kong.

For trade and other receivables, amounts due from related parties and contract assets, management makes periodic as well as individual assessments on the recoverability based on historical credit loss experience, as adjusted for forward looking information based on macroeconomic factors affecting the ability of the debtors to settle the receivables.

Management considers quantitative and qualitative factors and applies the simplified approach for the Group's trade receivables and contract assets without a significant financing component by using a lifetime expected loss provision.

The trade receivables and contract assets from customers with known financial difficulties or with significant doubt on collection of receivables are assessed individually for a loss allowance. As of December 31, 2021, the balance of loss allowance in respect of these individually assessed receivables was RMB1,296,000 (2020: RMB2,036,000).

Management assesses remaining customers by grouping them based on shared credit risk characteristics. Management determines an expected loss rate for each group based on historical credit loss experience as well as current and forecasts of future economic conditions in assessing the lifetime expected credit losses.

The expected loss rates are adjusted to reflect the different credit risk characteristics, timing of settlements, etc. related to those customers.

As of December 31, 2020	Within 6 months RMB'000	Between 6 months to 1 year RMB'000	Between 1 to 2 years RMB'000	Between 2 to 3 years RMB'000	After 3 years RMB'000	Total RMB'000
IVD product customers						
Expected loss rate	5 %	13 %	45 %	84 %	100 %	
Trade receivables and contract assets, gross	48,657	28,564	3,457	—	—	80,678
Loss allowance	2,641	3,790	1,571	—	—	8,002
Hospital customers						
Expected loss rate	4 %	4 %	7 %	22 %	100 %	
Trade receivables and contract assets, gross	13,028	9,329	13,660	625	53	36,695
Loss allowance	461	356	910	135	53	1,915
Other customers						
Expected loss rate	6 %	17 %	43 %	94 %	100 %	
Trade receivables and contract assets, gross	56,419	3,154	4,187	937	30	64,727
Loss allowance	3,202	546	1,819	882	30	6,479

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. Financial risk management (Continued)

3.1 Financial risk factors (Continued)

(b) Credit risk (Continued)

As of December 31, 2021	Within 6 months RMB'000	Between 6 months to 1 year RMB'000	Between 1 to 2 years RMB'000	Between 2 to 3 years RMB'000	After 3 years RMB'000	Total RMB'000
IVD product customers						
Expected loss rate	9 %	19 %	34 %	81 %	100 %	
Trade receivables and contract assets, gross	135,288	29,937	34,985	2,310	—	202,520
Loss allowance	11,984	5,628	11,896	1,880	—	31,388
Hospital customers						
Expected loss rate	13 %	14 %	29 %	55 %	100 %	
Trade receivables and contract assets, gross	19,872	9,784	17,046	13,521	612	60,835
Loss allowance	2,504	1,356	4,995	7,376	612	16,843
Other customers						
Expected loss rate	3 %	12 %	26 %	54 %	100 %	
Trade receivables and contract assets, gross	67,076	6,388	4,344	1,587	548	79,943
Loss allowance	1,859	765	1,144	863	548	5,179

In view of the history of cooperation with debtors and the sound collection history of other receivables and amounts due from related parties, management believes that the credit risk inherent in these outstanding receivables is not significant. There are no significant increases in credit risk of the receivables comparing with initial recognition and so the 12-month expected credit loss approach is adopted.

Loss allowance for trade and other receivables and contract assets were disclosed in Note 19, Note 20 and Note 6 respectively.

(c) Liquidity risk

The Group aims to maintain sufficient cash to meet obligations falling due as well as operating and capital requirements.

The tables below analyze the Group's financial liabilities into relevant maturity groupings based on the remaining period at each year-end date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
3. Financial risk management (Continued)
3.1 Financial risk factors (Continued)
(c) Liquidity risk (Continued)

	Less than 1 year RMB'000	Between 1 and 2 years RMB'000	Between 2 and 5 years RMB'000	Over 5 years RMB'000	Total RMB'000
As of December 31, 2020					
Borrowings	60,689	5,779	—	—	66,468
Lease liabilities	19,094	16,833	28,705	3,004	67,636
Trade payables	34,071	—	—	—	34,071
Other payables	56,206	—	—	—	56,206
Amounts due to related parties	24	—	—	—	24
Total	170,084	22,612	28,705	3,004	224,405
As of December 31, 2021					
Borrowings	20,206	—	—	—	20,206
Lease liabilities	22,811	19,850	16,351	1,682	60,694
Trade payables	55,767	—	—	—	55,767
Other payables	92,488	—	—	—	92,488
Amounts due to related parties	3	—	—	—	3
Other non-current liabilities	—	—	13,961	—	13,961
Total	191,275	19,850	30,312	1,682	243,119

3.2 Capital management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group monitors capital by regularly reviewing the capital structure. The Group may adjust the amount of dividends paid to shareholders, provide returns for shareholders, issue new shares or sell assets to repay borrowings.

The Group monitors capital on the basis of the debt-to-adjusted capital ratio. This ratio is calculated as net debt divided by adjusted capital. Net debt is calculated as total borrowings and lease liabilities less cash and cash equivalents. Adjusted capital comprises all components of equity as shown in the consolidated balance sheets. As of December 31, 2020 and 2021, the Group has no net debt outstanding.

3.3 Fair value estimation

The table below analyzes the Group's financial instruments carried at fair value as of December 31, 2020 and 2021 by level of the inputs to valuation techniques used to measure fair value. Such inputs are categorized into three levels within a fair value hierarchy as follows:

- (i) Quoted prices (unadjusted) in active markets for identical assets or liabilities (level 1).
- (ii) Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices) (level 2).
- (iii) Inputs for the asset or liability that are not based on observable market data (that is, unobservable inputs) (level 3).

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
3. Financial risk management (Continued)
3.3 Fair value estimation (Continued)

	Notes	Level 1 RMB'000	Level 2 RMB'000	Level 3 RMB'000	Total RMB'000
As of December 31, 2020					
Assets					
Financial assets at fair value through profit or loss					
— other investments	21(i)	—	—	19,609	19,609
— wealth management products	21(ii)	—	—	130,002	130,002
— equity security	21(iii)	10,292	—	—	10,292
Derivative financial instruments — foreign currency forwards	22	—	196	—	196
Total		10,292	196	149,611	160,099
As of December 31, 2021					
Assets					
Financial assets at fair value through profit or loss					
— other investments	21(i)	—	—	49,780	49,780
— wealth management products	21(ii)	—	—	144,361	144,361
— equity security	21(iii)	7,082	—	—	7,082
Derivative financial instruments — foreign currency forwards	22	—	2,002	—	2,002
Total		7,082	2,002	194,141	203,225

There were no transfers between levels 1, 2 and 3 during the reported periods.

Financial instruments in Level 3

If one or more of the significant inputs are not based on observable market data, the instrument is included in level 3.

Specific valuation techniques used to value financial instruments include:

- Quoted market prices or dealer quotes for similar instruments;
- Discounted cash flow model and unobservable inputs mainly including assumptions of expected future cash flows and discount rate; and
- A combination of observable and unobservable inputs, including risk-free rate, expected volatility, discount rate for lack of marketability, market multiples, etc.

Level 3 instruments of the Group's assets and liabilities include wealth management products and other investments measured at FVPL respectively.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
3. Financial risk management (Continued)
3.3 Fair value estimation (Continued)

The following table presents the movements in level 3 instruments for the reported periods.

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Wealth management products			
Opening balance	38,597	122,224	130,002
Additions	479,100	1,628,558	1,650,355
Gain/(loss) recognized in other income and gains – net (Note 9)	947	4,652	(5,867)
Redemptions	(396,420)	(1,625,106)	(1,628,463)
Exchange differences	—	(326)	(1,666)
Closing balance	122,224	130,002	144,361
Other investments			
Opening balance	—	—	19,609
Additions	—	19,000	28,895
Fair value change recognized in profit or loss (Note 9)	—	609	1,668
Exchange differences	—	—	(392)
Closing balance	—	19,609	49,780

The valuations of Level 3 instruments of wealth management products and other investments are set out in Note 21(ii) and Note 21(i), respectively.

The carrying amounts of the Group's other financial assets and liabilities, including cash and cash equivalents, trade and other receivables, trade and other payables, amounts due from/to related parties and borrowings, approximate their fair values.

4. Critical accounting estimates and judgments

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgment in applying the Group's accounting policies.

Estimates and judgments are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the Group and that are believed to be reasonable under the circumstances.

(a) Loss allowance of receivables

The Group applies the IFRS 9 simplified approach to measure expected credit losses which use a lifetime expected loss allowance and makes loss allowance based on assessments of the recoverability of the trade receivables and contract assets, including the current creditworthiness, the past collection history of each debtor and forward looking information. A considerable amount of judgment is required to estimate the expected loss rates. Where the actual result is different from the original estimate, such difference will impact the carrying value of the trade receivables and contract assets and loss allowances in the year in which such estimate is changed.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****4. Critical accounting estimates and judgments (Continued)****(b) Recognition of share-based compensation expenses**

As mentioned in Note 27, equity-settled share-based compensation plans have been granted to employees and consultants. The Group has used Binomial model to determine the total fair value of the awards, which is to be expensed over the vesting period. Significant estimate on assumptions, such as the fair value of underlying shares, risk-free interest rate, expected volatility, vesting period and dividend yield, is required to be made by the management.

(c) Fair value of financial instruments with preferred rights

The Group adopted the quoted market price of the Company's ordinary shares upon IPO on June 19, 2020 to measure the fair value of financial instruments with preferred rights immediately before their conversion into ordinary shares.

Prior to the IPO, the fair value of financial instruments with preferred rights that were not traded in an active market was determined using valuation techniques. The Group used the discounted cash flow method to determine the equity value of the Group and adopted equity allocation model to determine the fair value of the financial instruments with preferred rights. Key assumptions such as discount rate, risk-free interest rate and discount for lack of marketability ("DLOM") involved the use of significant accounting estimates and judgements.

(d) Current and deferred income taxes**(i) Deferred income tax**

The Group recognizes deferred tax assets based on estimates that it is probable to generate sufficient taxable profits in the foreseeable future against which the deductible losses will be utilized. The recognition of deferred tax assets mainly involves management's judgments and estimations about the timing and the amount of taxable profits of the companies which have tax losses.

(ii) Uncertain tax positions

There are many transactions and events for which the ultimate tax determination is uncertain during the ordinary course of business. Significant judgment is required from the Group in determining the provision for income taxes. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the income tax and deferred tax provisions in the period in which such determination is made.

In determining the amount of current and deferred income tax, the Group takes into account the impact of uncertain tax positions and whether preferential tax rates, additional taxes, interest or penalties may be due and whether future taxable profits will be available to enable deferred tax assets resulting from deductible temporary differences and tax losses to be recognized. This assessment relies on estimates and assumptions and may involve a series of judgments about future events. New information may become available that causes the Group to change its judgment regarding the adequacy of existing tax liabilities. Such changes to tax liabilities will impact tax expense in the period that such a determination is made.

(e) Consolidation of VIEs

The Group exercises control over the VIEs and has the right to recognize and receive substantially all the economic benefits through the Contractual Arrangements. The Group considers that it controls the VIEs notwithstanding the fact that it does not hold direct equity interests in the VIEs, as it has power over the VIEs and receives substantially all the economic benefits from the business activities of the VIEs through the Contractual Arrangements. Accordingly, the VIEs and subsidiaries of VIEs are accounted for as controlled structured entities and their financial statements have also been consolidated by the Company.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
5. Segment reporting

Management reviews the operating results of the business based on operating segments to make decisions about resources to be allocated. Management presents the following segments by which the CODM makes strategic decisions (Note 6):

- Diagnosis and monitoring – provision for LDT services
- Diagnosis and monitoring – sale of IVD products
- Development services

The major operating entities of the Group are domiciled in the PRC. Accordingly, substantially all of the Group's operating results were derived from the PRC during the reported periods. As of December 31, 2020 and 2021, substantially all of the Group's non-current assets were located in the PRC.

6. Revenue and segment information

	Diagnosis and monitoring – provision of LDT services RMB'000	Diagnosis and monitoring – sale of IVD products RMB'000	Development services RMB'000	Total RMB'000
Year ended December 31, 2019				
Revenue	234,569	34,915	53,941	323,425
Segment profit/(loss)	141,542	11,966	(8,518)	144,990
Year ended December 31, 2020				
Revenue	291,702	93,982	38,801	424,485
Segment profit	198,170	60,266	1,781	260,217
Year ended December 31, 2021				
Revenue	337,844	154,543	39,563	531,950
Segment profit	231,186	99,993	6,788	337,967

Reconciliation of segment profits to loss for the year:

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Total segment profits	144,990	260,217	337,967
Unallocated expenses			
— operating expenses	(451,860)	(528,593)	(855,815)
— finance (costs) /income – net	(9,221)	22,703	15,250
— losses from financial instruments with preferred rights	(359,943)	(2,823,370)	—
Loss for the year	(676,034)	(3,069,043)	(502,598)
	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Timing of revenue recognition			
— over time	204,406	265,137	218,754
— at a point in time	119,019	159,348	313,196
	323,425	424,485	531,950

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
6. Revenue and segment information (Continued)

The Group has recognized the following assets and liabilities related to contracts with customers:

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Contract assets	1,181	8,458
Less: loss allowance	(69)	(683)
	<u>1,112</u>	<u>7,775</u>
Contract liabilities	<u>8,417</u>	<u>11,962</u>
Revenue recognized that was included in the contract liabilities balance at the beginning of the year	<u>16,026</u>	<u>6,607</u>

Note:

Contract assets arise from provision of services ahead of the agreed payment schedules for fixed-price contracts. The contract assets were aged within one year with insignificant credit risk.

Contract liabilities mainly arise from the advance payments made by customers while the underlying services are yet to be provided. Most of these remaining obligations under such agreement are expected to be fulfilled within one year based on the estimation from management.

7. Expenses by nature

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Cost of inventories and consumables used (Note 17)	144,644	148,988	209,833
Employee benefit expenses (Note 8)	236,476	268,986	414,604
Depreciation on property, plant and equipment (Note 13)	30,458	33,466	36,865
Depreciation on right-of-use assets (Note 14)	14,784	18,277	23,821
Amortization on intangible assets (Note 15)	1,344	1,452	2,399
Loss allowance for trade and other receivables and contract assets	2,733	14,843	37,032
Promotion expenses	130,599	131,209	167,298
Rental, utilities and office expenses	9,663	16,347	27,472
Professional service fees	<u>44,664</u>	<u>36,135</u>	<u>88,829</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
8. Employee benefit expenses

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Wages, salaries and bonuses	153,815	195,462	279,443
Welfare expenses	8,866	8,637	10,711
Housing funds	11,465	14,799	21,299
Contributions to pension plans (Note)	26,446	20,137	49,007
Share-based compensation expenses (Note 27(d))	35,884	29,951	54,144
	<u>236,476</u>	<u>268,986</u>	<u>414,604</u>

Note:

The employees of the Group in the PRC are members of a state-managed pension scheme operated by the PRC Government. The Group is required to contribute a specified percentage of payroll costs as determined by local government authority to the pension obligations to fund the benefits. The only obligation of the Group with respect to the retirement benefits scheme is to make the specified contribution under the scheme. There were no significant forfeited contributions during the reported periods.

Employee benefit expenses were charged in the following categories in the consolidated statements of loss:

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Cost of revenue	27,375	27,108	35,589
Selling expenses	101,378	101,379	142,699
Administrative expenses	60,084	64,610	101,957
Research and development expenses	47,639	75,889	134,359
	<u>236,476</u>	<u>268,986</u>	<u>414,604</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

9. Other income and gains – net

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Investment income from wealth management products	723	4,182	4,925
Dividends from equity security	—	—	745
Fair value gain/(loss) on			
- wealth management products	224	470	(10,792)
- equity security	—	(3,153)	(3,011)
- other investments	—	609	1,668
- derivative financial instruments	—	196	2,002
Gain/(loss) on			
- settlement of derivative financial instruments	—	1,550	8,709
- disposal of property, plant and equipment	1,505	—	—
- disposal of right-of-use assets	—	—	(846)
- disposal of subsidiaries	—	—	2,305
Government grants (Note)	11,695	3,869	3,991
Amortization on deferred income from ADS depository (Note 29)	—	2,405	4,373
Donations	(1,090)	(2,327)	(9,866)
Others	240	725	1,126
	<u>13,297</u>	<u>8,526</u>	<u>5,329</u>

Note:

Government grants are subsidies received for compensating the Group's research and development expenses incurred for certain projects and other operating activities.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

10. Finance (costs)/income– net

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Finance income			
Interests from			
- bank deposits	198	433	1,189
- loans to a related party	243	—	—
- others	—	—	204
Net exchange gains	2,042	27,897	19,108
	<u>2,483</u>	<u>28,330</u>	<u>20,501</u>
Finance costs			
Issuance costs of financial instruments with preferred rights	(6,303)	—	—
Interests on			
- lease liabilities	(2,076)	(2,069)	(2,999)
- borrowings	(2,133)	(3,298)	(1,311)
- loans from a related party	(1,192)	—	—
- redemption liabilities (Note 31)	—	—	(941)
Others	—	(260)	—
	<u>(11,704)</u>	<u>(5,627)</u>	<u>(5,251)</u>
Finance (costs)/ income – net	<u>(9,221)</u>	<u>22,703</u>	<u>15,250</u>

11. Income tax expense

Income tax expense is recognized based on the income tax rates in the following main tax jurisdictions where the Group operates for the reported periods.

(a) Cayman Islands

The Company is incorporated in the Cayman Islands as an exempted company with limited liabilities under the Companies Law of Cayman Islands and accordingly, is exempted from Cayman Islands income tax.

(b) Hong Kong

No Hong Kong profit tax was provided for as there was no estimated assessable profit that was subject to Hong Kong profits tax during the reported periods.

(c) PRC

Provision for PRC corporate income tax is calculated based on the statutory income tax rate of 25% on the assessable income of respective PRC Group entities during the reported periods in accordance with relevant PRC enterprise income tax rules and regulations ("EIT Law") except for certain Group entities in PRC with preferential tax rates as detailed below.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
11. Income tax expense (Continued)
(c) PRC (Continued)

No provision for PRC corporate income tax has been made for the reported periods as the Group has no such assessable profit for the years.

The reconciliation between the Group's actual tax charge and the amount that is calculated based on the statutory income tax rate of 25% in the PRC is as follows:

	Year ended December 31,		
	2019	2020	2021
	RMB'000	RMB'000	RMB'000
Loss before income tax	(676,034)	(3,069,043)	(502,598)
Tax credits calculated at statutory tax rate of 25%	(169,009)	(767,261)	(125,650)
Effects of preferential tax rates and different tax rates in other jurisdictions (Note (i))	37,139	18,900	51,843
Expenses not deductible for income tax purpose (Note (ii))	101,536	722,458	29,102
Super deduction of research and development expenses	(6,273)	(8,390)	(11,416)
Tax losses and deductible temporary differences for which no deferred income tax assets were recognized	36,607	34,293	56,121
Income tax expense	—	—	—

Note:

- (i) Certain Group entities in PRC have been eligible as High/New Technology Enterprises with preferential tax rate of 15% as set out in PRC EIT Law.
- (ii) These mainly include fair value loss of financial instruments with preferred rights during 2019 and 2020.

The Group did not recognize deferred income tax assets amounting to approximately RMB140 million and RMB196 million as of December 31, 2020 and 2021 respectively in respect of tax losses and deductible temporary differences that can be carried forward against future taxable income.

The unrecognized tax losses of approximately RMB840 million and RMB1,188 million as of December 31, 2020 and 2021 will progressively expire until 2030 and 2031 respectively.

As of December 31, 2020 and 2021, the Group did not have any significant unrecognized uncertain tax positions.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
12. Loss per share

Basic and diluted loss per share reflecting the effect of the issuance of ordinary shares by the Company are presented as follows.

To calculate loss per share, the capital structure in July 2019 when the Reorganization completed is pushed back assuming it had been in effect historically as stated in Note 1.3. Basic loss per share is calculated by dividing the loss attributable to owners of the Company by the weighted average number of ordinary shares outstanding, excluding treasury shares which are detailed in Note 25. Restricted ordinary shares have been considered in the calculation when they vested on monthly basis.

	Year ended December 31,		
	2019	2020	2021
Loss attributable to owners of the Company (RMB'000)	(676,034)	(3,069,043)	(496,238)
Weighted average number of ordinary shares outstanding (in thousands) (Note)	124,895	301,380	460,547
Basic loss per share (RMB)	(5.41)	(10.18)	(1.08)
Basic loss per ADS (RMB)		(50.92)	(5.39)

Awards granted under share-based compensation plans and Preferred Shares are considered as potential dilutive shares throughout the reporting periods. However, due to the Group's negative financial results for the reported periods, the potential dilutive shares have anti-dilutive effect on loss per share if they are converted to ordinary shares. Thus diluted loss per share/ADS is equivalent to basic loss per share/ADS.

Note:

Movement of number of ordinary shares outstanding (excluding treasury shares) for the reported periods are shown as follows.

	Year ended December 31,		
	2019 in thousands	2020 in thousands	2021 in thousands
At beginning of the year	119,812	123,584	456,707
Ordinary shares			
— repurchased	(8,272)	—	—
— issued upon IPO	—	80,000	—
— converted from Preferred Shares upon IPO	—	220,332	—
Restricted shares vested*	12,044	17,894	—
Awards vested**	—	14,897	6,162
At end of the year	123,584	456,707	462,869

* considered in the calculation when they vested on monthly basis

** represent awards with nominal subscription prices which have been vested but not yet exercised at end of the year

13. Property, plant and equipment

	Instruments and equipment RMB'000	Office equipment and furniture RMB'000	Transporting equipment RMB'000	Leasehold improvements RMB'000	Total RMB'000
As of January 1, 2019					
Cost	121,895	2,967	445	18,871	144,178
Accumulated depreciation	(49,700)	(1,143)	(53)	(10,731)	(61,627)
Net book value	72,195	1,824	392	8,140	82,551
Year ended December 31, 2019					
Opening net book value	72,195	1,824	392	8,140	82,551
Additions	27,766	986	24	2,210	30,986
Disposals	(173)	—	—	—	(173)
Depreciation	(25,332)	(611)	(113)	(4,402)	(30,458)
Exchange differences	107	—	—	—	107
Closing net book value	74,563	2,199	303	5,948	83,013
As of December 31, 2019					
Cost	147,658	3,953	469	21,081	173,161
Accumulated depreciation	(73,095)	(1,754)	(166)	(15,133)	(90,148)
Net book value	74,563	2,199	303	5,948	83,013
Year ended December 31, 2020					
Opening net book value	74,563	2,199	303	5,948	83,013
Additions	19,573	908	—	6,896	27,377
Depreciation	(28,038)	(784)	(112)	(4,532)	(33,466)
Exchange differences	(33)	—	—	—	(33)
Closing net book value	66,065	2,323	191	8,312	76,891
As of December 31, 2020					
Cost	167,085	4,861	469	27,977	200,392
Accumulated depreciation	(101,020)	(2,538)	(278)	(19,665)	(123,501)
Net book value	66,065	2,323	191	8,312	76,891
Year ended December 31, 2021					
Opening net book value	66,065	2,323	191	8,312	76,891
Additions	58,169	1,683	—	10,827	70,679
Disposals	(313)	(54)	—	(35)	(402)
Depreciation	(29,729)	(910)	(112)	(6,114)	(36,865)
Exchange differences	(17)	(1)	—	—	(18)
Closing net book value	94,175	3,041	79	12,990	110,285
As of December 31, 2021					
Cost	222,203	5,971	469	36,652	265,295
Accumulated depreciation	(128,028)	(2,930)	(390)	(23,662)	(155,010)
Net book value	94,175	3,041	79	12,990	110,285

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
14. Leases

(a) Amounts recognized in the consolidated balance sheets are as follows:

(i) **Right-of-use assets**

	Properties RMB'000	Office equipment RMB'000	Total RMB'000
As of January 1, 2019			
Cost	42,561	50	42,611
Year ended December 31, 2019			
Opening net book value	42,561	50	42,611
Additions	15,355	—	15,355
Depreciation	(14,766)	(18)	(14,784)
Closing net book value	43,150	32	43,182
As of December 31, 2019			
Cost	57,916	50	57,966
Accumulated depreciation	(14,766)	(18)	(14,784)
Net book value	43,150	32	43,182
Year ended December 31, 2020			
Opening net book value	43,150	32	43,182
Additions	34,801	—	34,801
Depreciation	(18,259)	(18)	(18,277)
Closing net book value	59,692	14	59,706
As of December 31, 2020			
Cost	92,717	50	92,767
Accumulated depreciation	(33,025)	(36)	(33,061)
Net book value	59,692	14	59,706
Year ended December 31, 2021			
Opening net book value	59,692	14	59,706
Additions	17,495	—	17,495
Disposals	(719)	—	(719)
Depreciation	(23,807)	(14)	(23,821)
Exchange differences	(587)	—	(587)
Closing net book value	52,074	—	52,074
As of December 31, 2021			
Cost	101,469	—	101,469
Accumulated depreciation	(49,395)	—	(49,395)
Net book value	52,074	—	52,074

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
14. Leases (Continued)

(a) Amounts recognized in the consolidated balance sheets are as follows (Continued):

(ii) **Lease liabilities**

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Non-current	43,016	33,865
Current	16,585	20,572
	<u>59,601</u>	<u>54,437</u>

(b) Amounts recognized in the consolidated statements of loss in addition to depreciation shown above are as follows:

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Interest expense (included in finance costs) (Note 10)	2,076	2,069	2,999
Expense relating to short-term leases (included in cost of revenue, selling expenses, administrative expenses and research and development expenses)	621	530	2,413
Expense relating to leases of low-value assets that are not shown above as short-term leases (included in cost of revenue, selling expenses, administrative expenses and research and development expenses)	<u>403</u>	<u>521</u>	<u>214</u>

(c) The total cash outflows for leases in 2019, 2020 and 2021 was RMB15,234,000, RMB22,726,000 and RMB27,298,000, respectively.

15. Intangible assets

	Software RMB'000	Patented technology RMB'000	Others RMB'000	Total RMB'000
As of January 1, 2019				
Cost	4,200	230	2,030	6,460
Accumulated amortization and impairment	(1,313)	(230)	(1,522)	(3,065)
Net book value	2,887	—	508	3,395
Year ended December 31, 2019				
Opening net book value	2,887	—	508	3,395
Additions	3,376	—	—	3,376
Amortization	(836)	—	(508)	(1,344)
Exchange differences	55	—	—	55
Closing net book value	5,482	—	—	5,482
As of December 31, 2019				
Cost	7,679	230	2,030	9,939
Accumulated amortization and impairment	(2,197)	(230)	(2,030)	(4,457)
Net book value	5,482	—	—	5,482
Year ended December 31, 2020				
Opening net book value	5,482	—	—	5,482
Additions	8,253	—	—	8,253
Amortization	(1,452)	—	—	(1,452)
Exchange differences	(18)	—	—	(18)
Closing net book value	12,265	—	—	12,265
As of December 31, 2020				
Cost	15,798	230	2,030	18,058
Accumulated amortization and impairment	(3,533)	(230)	(2,030)	(5,793)
Net book value	12,265	—	—	12,265
Year ended December 31, 2021				
Opening net book value	12,265	—	—	12,265
Additions	10,849	—	—	10,849
Amortization	(2,399)	—	—	(2,399)
Exchange differences	(20)	—	—	(20)
Closing net book value	20,695	—	—	20,695
As of December 31, 2021				
Cost	26,582	230	2,030	28,842
Accumulated amortization and impairment	(5,887)	(230)	(2,030)	(8,147)
Net book value	20,695	—	—	20,695

16. Financial instruments by category

Financial assets	Financial assets at FVPL RMB'000	Financial assets at amortized cost RMB'000	Total RMB'000
As of December 31, 2020			
Trade receivables	—	164,592	164,592
Other receivables	—	11,968	11,968
Amounts due from related parties	—	214	214
Financial assets at fair value through profit or loss	159,903	—	159,903
Derivative financial instruments	196	—	196
Cash and cash equivalents	—	1,375,766	1,375,766
	<u>160,099</u>	<u>1,552,540</u>	<u>1,712,639</u>
As of December 31, 2021			
Trade receivables	—	282,113	282,113
Other receivables	—	34,595	34,595
Amounts due from related parties	—	597	597
Financial assets at fair value through profit or loss	201,223	—	201,223
Derivative financial instruments	2,002	—	2,002
Cash and cash equivalents	—	639,042	639,042
	<u>203,225</u>	<u>956,347</u>	<u>1,159,572</u>
Financial liabilities	Financial liabilities at FVPL RMB'000	Financial liabilities at amortized cost RMB'000	Total RMB'000
As of December 31, 2020			
Borrowings	—	64,076	64,076
Lease liabilities	—	59,601	59,601
Trade payables	—	34,071	34,071
Other payables	—	56,206	56,206
Amounts due to related parties	—	24	24
	<u>—</u>	<u>213,978</u>	<u>213,978</u>
As of December 31, 2021			
Borrowings	—	19,554	19,554
Lease liabilities	—	54,437	54,437
Trade payables	—	55,767	55,767
Other payables	—	92,488	92,488
Amounts due to related parties	—	3	3
Other non-current liabilities	—	8,612	8,612
	<u>—</u>	<u>230,861</u>	<u>230,861</u>

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
17. Inventories

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Raw materials	14,078	23,251
Work-in-progress	5,265	2,260
Finished goods	5,628	10,092
	<u>24,971</u>	<u>35,603</u>

Inventories recognized as expenses during each of the years ended December 31, 2019, 2020 and 2021 amounted to RMB144,644,000, RMB148,988,000 and RMB209,833,000 respectively, most of which are included in cost of revenue in consolidated statements of loss.

18. Other current assets

These include deductible value-added tax ("VAT") balances which can offset against future VAT payables.

19. Trade receivables

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Trade receivables, gross	182,955	336,136
Less: loss allowance	(18,363)	(54,023)
	<u>164,592</u>	<u>282,113</u>

Trade receivables are generally due for settlement within 30 days, except for those of IVD product sales up to 12 months. As of December 31, 2020 and 2021, majority of the trade receivables are aged within one year. The expected credit losses of trade receivables and the Group's exposure to credit risk are disclosed in Note 3.1(b).

20. Other receivables and prepayments

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Deposits	7,603	7,344
Prepayment for goods and service	27,568	59,058
Prepayment for rental expenses	694	536
Others	7,032	31,431
	<u>42,897</u>	<u>98,369</u>
Less: loss allowance	(477)	(474)
	<u>42,420</u>	<u>97,895</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

21. Financial assets at fair value through profit or loss

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Non-current		
Other investments (Note (i))	19,609	49,780
Current		
Wealth management products (Note (ii))	130,002	144,361
Equity security (Note (iii))	10,292	7,082
	<u>140,294</u>	<u>151,443</u>

Note:

- (i) In 2020 the Group invested RMB19 million in a biotechnology company and thereby obtained 30% of its equity interests with certain preferred rights in redemption, liquidation and anti-dilution. As such this is investment in an associate being designated as financial assets at FVPL.

In 2021 the Group further invested RMB29 million in total in other biotechnology companies which are classified as financial assets at FVPL.

Above fair values are measured based on discounted cash flow method.

- (ii) Wealth management products held by the Group with various maturities bear floating interest rates at ranges of 2.30%—2.40% and 1.40%—3.76% per annum as of December 31, 2020 and 2021 respectively. The underlying investments were mostly debt instruments with low to moderate risk levels. The fair values of wealth management products are based on discounted cash flows using their expected returns.
- (iii) This is investment of an equity security listed in Hong Kong held for trading with purchase cost of approximately RMB14 million. Its fair value at end of reporting period is determined by closing price quoted in an active stock market.

Changes in fair values of these financial assets are recorded in other income and gains/(losses) — net in the consolidated statements of loss.

22. Derivative financial instruments

The Group has entered into foreign currency forwards to sell US\$ and buy RMB with maturities within one year.

The fair values of these foreign currency forwards are based on the present value of the estimated future cash flows by reference to forward exchange rates and other factors at the balance sheet date.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

23. Cash and cash equivalents

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Cash at bank		
-RMB deposits	20,433	365,613
-US\$deposits	1,355,276	273,402
-HK\$deposits	57	27
	<u>1,375,766</u>	<u>639,042</u>

Cash at banks earns interest at floating rates based on daily bank deposit rates.

Cash at banks denominated in RMB are deposited with banks in the PRC. The conversion of these RMB-denominated balances into foreign currencies and the remittance of funds out of China are subject to the rules and regulations of foreign exchange control promulgated by the Government of the PRC.

24. Share capital and share premium

	Note	Number of ordinary shares	Nominal value of ordinary shares US\$'000	Number of preferred shares	Nominal value of preferred shares US\$'000
Authorized:					
As of January 1, 2019		500,000,000	50	—	—
Share sub-division	(i)	2,000,000,000	—	—	—
Re-designation upon issuance of then preferred shares at share conversion	(ii)	(171,083,000)	(3)	171,083,000	3
Shares repurchase and issuance					
- repurchase	(iv)	(8,272,000)	—	(6,933,000)	—
- issuance	(iv)	—	—	15,205,000	—
Re-designation upon issuance of Series D preferred shares	(v)	(34,147,600)	(1)	34,147,600	1
As of December 31, 2019		<u>2,286,497,400</u>	<u>46</u>	<u>213,502,600</u>	<u>4</u>
As of January 1, 2020		2,286,497,400	46	213,502,600	4
Re-designation upon issuance of Series D-2 preferred shares	(vi)	(6,829,500)	—	6,829,500	—
Conversion of preferred shares into ordinary shares	(vii)	220,332,100	4	(220,332,100)	(4)
As of December 31, 2020 and December 31, 2021		<u>2,500,000,000</u>	<u>50</u>	<u>—</u>	<u>—</u>

24. Share capital and share premium (Continued)

	Note	Number of ordinary shares	Nominal value of ordinary shares (Share capital)		Share premium
			US\$'000	RMB'000	RMB'000
Issued:					
As of January 1, 2019		3	—	—	—
Share repurchase	(i)	(2)	—	—	—
Share sub-division	(i)	4	—	—	—
Issuance of ordinary shares	(iii)	149,749,995	3	18	—
Repurchase of ordinary shares	(iv)	(8,272,000)	—	(1)	—
As of December 31, 2019		141,478,000	3	17	—
As of January 1, 2020					
Issuance of ordinary shares upon IPO	(vii)	141,478,000	3	17	—
Conversion of preferred shares into ordinary shares	(vii)	80,000,000	2	11	1,657,782
		220,332,100	4	31	4,999,780
As of December 31, 2020		441,810,100	9	59	6,657,562
As of January 1, 2021					
Exercise of awards	27(a)	441,810,100	9	59	6,657,562
		11,164,880	—	2	53,672
As of December 31, 2021		452,974,980	9	61	6,711,234

Note:

- (i) On July 2, 2019, the Company repurchased 2 ordinary shares and conducted a 1:5 share sub-division to amend its authorized share capital to 2,500,000,000 ordinary shares with a par value of US\$0.00002 each in accordance with the resolution of the shareholders of the Company.
- (ii) On July 2, 2019, the Company issued 171,083,000 preferred shares (equivalent to then 34,216,600 preferred shares of Genetron Health with each share having been converted to five shares of the Company) at par value of US\$0.00002 per share.
- (iii) On July 2, 2019, the Company further issued 149,749,995 ordinary shares to each of the then equity holders of Genetron Health with substantially the same rights and shareholding percentages in Genetron Health upon the Reorganization. Together with the 5 ordinary shares of the Company resulted from (i) and (ii) above, this totalled 149,750,000 ordinary shares of the Company, with each share of Genetron Health having been converted to five shares of the Company.
- (iv) In November 2019 the Group repurchased 8,272,000 ordinary shares and 6,933,000 preferred shares from certain then shareholders including the Founders for an aggregate consideration of US\$15 million, and issued 15,205,000 Series C-2 preferred shares to a new investor ("C-2 investor") for the same amount of consideration.

Consequently the total nominal value of ordinary shares repurchased of US\$165 (equivalent to approximately RMB1,000) was deducted from share capital, and the excess of the relevant portion of consideration paid over the total nominal value of repurchased ordinary shares of US\$8,160,000 (equivalent to approximately RMB57,438,000) was debited to (a) the balance standing to then capital reserve of RMB35,174,000 and (b) other reserve of RMB22,264,000.

GENETRON HOLDINGS LIMITED**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****24. Share capital and share premium (Continued)**

Note (Continued):

- (v) In November 2019 the Company further issued 34,147,600 Series D preferred shares for an aggregate consideration of US\$50 million to certain investors including the C-2 investor.
- (vi) In February 2020 the Company further issued 6,829,500 Series D-2 preferred shares for a cash consideration of US\$10 million.
- (vii) On June 19, 2020, 16,000,000 ADSs (representing 80,000,000 ordinary shares) were offered by the Company upon their listing on NASDAQ. Simultaneously all the 220,332,100 then preferred shares of the Company were converted into ordinary shares.

25. Treasury shares

A total of 93,506,000 ordinary shares of the Company held by the Founders were put in escrow with service conditions and vested on monthly basis or by one tranche which are detailed in Note 27(b) and Note 27(c) respectively. As of December 31, 2020 and December 31, 2021, all the ordinary shares in escrow were vested and released.

26. Reserves**(a) Capital reserve**

Capital reserve mainly included historical cash contributions to Genetron Health by its equity holders.

On August 28, 2017, a Founder invested RMB2,173,600 to Genetron Health in cash to subscribe for 2,173,600 ordinary shares of Genetron Health, details of which are set out in Note 27(c).

In November 2019 the Group repurchased certain ordinary shares with the excess of consideration paid over their nominal value being debited to the balances standing to then capital reserve and other reserve of the Group as detailed in Note 24(iv).

(b) Share-based compensation reserve

The share-based compensation reserve represents the fair value of the actual or estimated number of unvested restricted shares and unexercised awards granted to employees recognized in accordance with the accounting policy adopted for equity-settled share-based payments in Note 2.21 to the financial statements.

(c) Other reserve

Other reserve includes the reserve transferred from share-based compensation reserve upon vesting of restricted shares.

(d) Other comprehensive losses

Other comprehensive losses comprise the exchange translation reserve which represents the foreign exchange differences arising from the translation of the financial statements of foreign operations in accordance with the accounting policy set out in Note 2.5(c) to the financial statements, and changes in the fair value of the financial instruments with preferred rights which are attributable to changes in the credit risk of that liability set out in Note 2.18.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

26. Reserves (Continued)**(e) Statutory reserves**

In accordance with the PRC regulations and the articles of association of the PRC companies now comprising the Group, before annual profit distribution companies registered in the PRC are required to set aside 10% of its net profit for the year after offsetting any prior year losses as determined under relevant PRC accounting standards to the statutory surplus reserve fund. When the balance of such reserve reaches 50% of the company's registered capital, any further appropriation is optional. No profit appropriation to the reserve fund was made for those Group entities for the reported periods as they were in accumulated loss positions.

27. Share-based payment**(a) Share Incentive Plan and Share Incentive Scheme**

Genetron Health had two previous employee share incentive plans for its key employees, key management and consultants, which were approved by its board of directors and became effective in January 2017 and June 2018, respectively. The purpose is to provide incentives and rewards to eligible participants for their contribution or potential contribution to the Group and to recruit and retain high calibre persons who are valuable to the Group. The incentive shares had included 6,792,300 shares of Genetron Health (equivalent to 33,961,500 shares of the Company with each share of Genetron Health having been converted to five shares of the Company in July 2019).

In July 2019, the Group adopted the 2019 Genetron Health Share Incentive Plan (the "2019 Plan") under which the awards completely replaced all options granted under previous similar share incentive plans. In October 2019, the Group further adopted the 2019 Genetron Health Share Incentive Scheme (the "2019 Scheme") with substantially the same terms. The 2019 Plan and 2019 Scheme provide for the issuance of up to an aggregate of 33,961,500 and 20,830,100 of the Company's ordinary shares respectively, out of which 22,555,620 and 21,340,740 ordinary shares have been issued but deemed not outstanding as of December 31, 2020 and 2021, respectively.

Pursuant to the plans, a grantee has the right to subscribe for the ordinary shares at a price determined by the board of directors of the Company. The awards granted can only vest if the performance conditions (including certain annual performance rating and sales or development performance indicator, which have been defined on grant date) and service conditions are met. The service condition of the awards granted to employees and key management is usually four years since the grant date and 25% of the granted awards are progressively vested on each anniversary of the grant date. The service condition for consultants is one to three years. The grantees are entitled to subscribe for underlying shares only if an IPO is achieved, provided that the service condition is also met. As of each grant date before IPO on June 19, 2020, management believed achievement of the IPO was probable. Grantees who leave the Group before the exercisable date will lose their entitlement to the vested awards. Awards granted typically expire in ten years from the grant date as stated in grant agreements.

Participation in the plans is at the discretion of the board of directors of the Company and no individual has contractual right to participate in the plans or receive any guaranteed benefits.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
27. Share-based payment (Continued)
(a) Share Incentive Plan and Share Incentive Scheme (Continued)

Set out below are movements of awards during the reported periods.

	Year ended December 31,					
	2019		2020		2021	
	Exercise price	Number of awards	Exercise price (Note (iii))	Number of awards	Exercise price (Note (iii))	Number of awards
Outstanding at beginning of the year	RMB1.00	4,578,933	US\$0.03	23,481,970	US\$0.13	26,216,268
Granted during the year	RMB1.00	713,840	US\$0.88	3,035,000	US\$0.96	2,701,746
Exercised during the year	—	—	—	—	US\$0.03	(11,164,880)
Forfeited before Reorganization (Note (i))	RMB1.00	(47,507)	—	—	—	—
Share sub-division upon Reorganization (Note 24(i))	US\$0.03	18,321,704	—	—	—	—
Forfeited after Reorganization (Note (i))	US\$0.03	(85,000)	US\$0.03	(300,702)	US\$0.14	(296,835)
Outstanding at end of the year	US\$0.03	23,481,970	US\$0.13	26,216,268	US\$0.32	17,456,299
Exercisable at end of the year (Note (ii))	—	—	US\$0.03	14,897,089	US\$0.10	10,006,742

Note:

- (i) The shares are forfeited if the employment terminates or the performance condition is not met.
- (ii) Awards are only exercisable upon completion of IPO or after other vesting periods.
- (iii) Exercise prices are shown as weighted average as applicable.

The weighted average remaining contractual lives of awards outstanding as of December 31, 2019, 2020 and 2021 are 8.0 years and 7.3 years and 6.9 years, respectively.

Fair value of awards granted

The Group used the discounted cash flow method to determine the underlying equity fair value and adopted equity allocation model to determine the fair value of the underlying ordinary shares prior to IPO, subsequent to which the fair value of the shares is calculated based on the quoted market price of the Company's shares at the respective grant date.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
27. Share-based payment (Continued)
(a) Share Incentive Plan and Share Incentive Scheme (Continued)

Based on the fair value of underlying ordinary shares, the Group used Binominal option-pricing model to determine the fair value of awards as of each of the grant dates. Key assumptions for the awards granted are set as below:

Year of grant	Before July 2019	After July 2019	2020	2021
Fair values at grant date				
- (RMB per share of Genetron Health) (Note)	36.32	—	—	—
- (US\$per share of the Company) (Note)	—	1.25	1.76 - 2.38	1.96 - 4.51
Exercise prices				
- (RMB per share of Genetron Health) (Note)	1.00	—	—	—
- (US\$per share of the Company) (Note)	—	0.03	0.03 - 0.99	0.03 - 0.99
Risk-free interest rates	2.09 %	1.69 %	0.64 % - 0.67 %	1.48 % - 1.67 %
Dividend yield	nil	nil	nil	nil
Expected volatilities	50.20 %	48.80 %	54.90 % - 55.10 %	53.40 % - 55.60 %
Expected term	10 years	10 years	10 years	10 years

Note:

Each share of Genetron Health was converted to five shares of the Company upon the Reorganization in July 2019 when the exercise price of all then existing awards was modified from RMB1.00 per share of Genetron Health to US\$0.03 per share of the Company without impact on their values.

(b) Restriction of ordinary shares held by Founders

On May 7, 2015, an aggregate of 16,527,600 ordinary shares of Genetron Health at par value of RMB1.00 per share were issued to three directors, who are also Founders of Genetron Health. In accordance with Series A financing agreement on July 17, 2015, all the 16,527,600 ordinary shares held by the individual Founders were put in escrow since that date with a five-year service condition (which was subsequently fulfilled during 2020). Such restriction was deemed as a compensatory arrangement for services to be provided by the Founders and therefore accounted for as a share-based compensation arrangement.

The Group applied Binomial model to determine the fair value of this share-based payment as RMB3.12 per share on the grant date. Key assumptions included risk-free interest rate of 1.70%, expected volatility of 50.00%, dividend yield of nil and expected terms of 5 years based on best estimates.

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

27. Share-based payment (Continued)

(b) Restriction of ordinary shares held by Founders (Continued)

As modified since Series B financing in September 2016, one sixtieth of the award became vested on a monthly basis over five years provided that the Founders remained employment relationship with Genetron Health. Under the Series C financing in October 2017, the shares owned by one of the Founders were no longer subject to the five-year service condition and his then 2,540,650 restricted shares were vested immediately on the modification date. Accordingly, the unrecognized grant date fair value of those shares were accelerated and recognized as share-based compensation expenses on the modified date.

If the Founders terminated service, the Group had to repurchase the shares put in escrow at RMB1.00 per share, which was considered a leaver provision and recorded in other payables and accruals to be released proportionally as the restricted shares were progressively released from escrow.

The movement of the restricted shares for the years ended December 31, 2019, 2020 and 2021 are summarized as below:

	Number of restricted shares (in thousands)
Outstanding at January 1, 2019	3,813
Vested and released before Reorganization	(1,204)
Share sub-division upon Reorganization (Note 24(i))	10,439
Vested and released after Reorganization	(6,024)
Outstanding at December 31, 2019	7,024
Outstanding at January 1, 2020	7,024
Vested and released	(7,024)
Outstanding at December 31, 2020 and December 31, 2021	—

(c) Share-based payment to a Founder

Pursuant to the Series A preferred shares agreement in July 2015, a Founder was granted the right to subscribe for shares of Genetron Health amounted to 3% to 5% of its total shares outstanding at par value of RMB1.00 per share if the appraised value of Genetron Health reached RMB590 million before Series B preferred shares financing. The shares had a five-year service condition (which was subsequently fulfilled during 2020).

The market condition of target appraised value was met in 2016 and the Founder was allowed to subscribe for 2,173,600 shares (representing 5% of the total number of ordinary and preferred shares then outstanding) of Genetron Health at RMB1.00 per share. The shares were paid up in 2017 and the funds received represent a leaver provision being recorded in other payables and accruals as Genetron Health had to pay such amount to repurchase the shares if the service condition was not met.

The Group applied Binomial model to determine the fair value of this share-based payment as RMB1.79 per share on the grant date. Key assumptions included probability of achieving the market condition, risk-free interest rate of 0.51%, expected volatility of 55.80%, dividend yield of nil and expected terms of 1.5 years based on best estimates.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
27. Share-based payment (Continued)

- (d) Share-based compensation expenses were charged in the following categories in the consolidated statements of loss:

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Cost of revenue	446	300	808
Selling expenses	2,720	3,906	15,243
Administrative expenses	25,940	15,013	19,346
Research and development expenses	6,778	10,732	18,747
	<u>35,884</u>	<u>29,951</u>	<u>54,144</u>

28. Borrowings

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Non-current		
Other borrowings (Note (i))	5,493	—
Current		
Bank borrowings (Note (ii))	50,000	15,153
Current portion of other borrowings (Note (i))	8,583	4,401
	<u>58,583</u>	<u>19,554</u>
Total	<u>64,076</u>	<u>19,554</u>

Note:

- (i) The Group entered into sale and leaseback agreements with independent parties, to which the Group transferred the ownership of certain instruments and thereby obtained cash proceeds ("consideration") with the following details:

Date	Term	Consideration RMB'000	Guarantee/pledge
March 2019	2 year	25,000	(a)
June 2019	3 year	6,960	(b)
July 2020	2 year	12,800	(c)

(a) guarantee provided by a director of the Group and pledge of all equity interest of Beijing Genetron Medical Laboratory Co., Ltd., a subsidiary of the Company

(b) corporate guarantee provided by Genetron Health

(c) guarantee provided by a director of the Group

The Group continues to have control over the assets which make the above ownership transfers not qualify as sales transactions as a result. The proceeds received by the Group are thus in substance borrowings with the assets not being derecognized.

The interest rates of these borrowings are approximately 6%-8% per annum and subject to adjustments in accordance with the benchmark lending interest rate promulgated by the People's Bank of China. The principals and interests are repaid in quarterly or monthly instalments based on respective agreements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
28. Borrowings (Continued)

Note (Continued):

(ii) The Group obtained bank facilities by which loan amounts were drawn with following details:

Date of obtaining facility	Facility term	Facility amount RMB'000	Loan amount drawn RMB'000	Loan period	Guarantee /pledge	Interest rate (per annum)
June 2019	2 year	5,000	5,000	June 2019 – June 2020	(a)	5.0 %
March 2020	1 year	10,000	10,000	March 2020 – March 2021	(b)	3.7 %
March 2020	1 year	30,000	30,000	March 2020 – March 2021	(c)	2.0 %
May 2020	2 year	25,000	10,000	October 2020 – October 2021	(d)	3.5 %
February 2021	1 year	10,000	10,000	February 2021 – February 2022	(c)	3.9 %
November 2021	1 year	20,000	15,707	November 2021 – November 2022	(e)	3.9 %

- (a) guaranteed by an independent party (the “guarantor”), to which each of Mr. Sizhen Wang (a director of the Group) and Genetron Health have provided counter-guarantees, in addition to a facility fee of RMB110,000 paid by the Group. To provide the counter-guarantee Genetron Health has to pledge not less than RMB10 million of certain of its receivables to the guarantor.
- (b) guaranteed by an independent party, to which Mr. Sizhen Wang has provided counter-guarantee, in addition to a facility fee of RMB130,000 paid by the Group.
- (c) guaranteed by Mr. Sizhen Wang.
- (d) guaranteed by an independent party (the “guarantor”), to which each of Mr. Sizhen Wang, Genetron Health and certain of its subsidiaries have provided counter-guarantees, in addition to a facility fee of RMB138,000 paid by the Group. To provide the counter-guarantees Genetron Health and certain of its subsidiaries have to pledge a patented technology and not less than RMB20 million of certain of Genetron Health’s receivables to the guarantor.
- (e) corporate guarantee provided by Genetron TJ.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
29. Other payables and accruals

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Payroll and welfare payables	30,625	42,612
Accrued professional service fees and listing expenses	10,437	35,368
Accrued taxes other than income tax	1,668	2,583
Deferred income from ADS depository (Note)	19,766	14,995
Others	48,668	61,674
	<u>111,164</u>	<u>157,232</u>

Note:

After listing in 2020 the Company entered into an agreement with a bank to deposit its ADSs for 5 years (the “deposit period”) and received a fee of US\$3.4 million (equivalent to approximately RMB23 million) which is to be amortized over the deposit period.

30. Financial instruments with preferred rights

The Group had completed a series of financing by issuing shares with preferred rights including conversion feature, liquidation preferences and redemption rights (“Preferred Shares”), of which the preferred shares issued by Genetron Health before July 2019 were converted to shares of the Company on one-for-five basis upon the Reorganization, with following details:

Date of subscription	Round	Note	Number of Preferred Shares of the Company (in thousands)	Subscription/ (repurchase) consideration RMB'000
July 17, 2015	Series A-1		39,200	70,000
August 6, 2015	Series A-1		8,400	15,000
September 24, 2015	Series A-2		19,760	50,000
September 18, 2016	Series B		25,358	100,000
November 2, 2016	Series B		18,005	71,000
October 10, 2017	Series C		51,525	350,000
December 29, 2017	Series C		8,835	60,000
November 18, 2019	Series A-1, A-2, B	24(iv)	(6,933)	(48,105)
November 19, 2019	Series C-2	24(iv)	15,205	105,325
November 19, 2019	Series D	24(v)	34,148	351,243
February 19, 2020	Series D-2	24(vi)	6,829	70,026
			<u>220,332</u>	

The Group designated the entire instruments as financial liabilities at FVPL with the changes in the fair value recorded in the consolidated statements of loss, except for the changes in fair value due to own credit risk, which were recorded in other comprehensive losses. The accumulated fair value change due to own credit risk amounting to RMB27,355,000 was reclassified to accumulated losses upon conversion of these financial instruments with preferred rights into ordinary shares in 2020.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
30. Financial instruments with preferred rights (Continued)

Movements of financial instruments with preferred rights during the years ended December 31, 2019, 2020 and 2021 are:

	RMB'000
Year ended December 31, 2019	
At January 1, 2019	1,320,712
Repurchase of Series A-1, A-2, B preferred shares	(48,105)
Issuance of Series C-2 preferred shares	105,325
Issuance of Series D preferred shares	351,243
Changes in fair value recognized in profit or loss	333,401
Changes in fair value due to own credit risk recognized in OCI	17,299
Other loss	26,542
Exchange differences	(83)
At December 31, 2019	2,106,334
Year ended December 31, 2020	
At January 1, 2020	2,106,334
Issuance of Series D-2 preferred shares	70,026
Changes in fair value recognized in profit or loss	2,823,370
Changes in fair value due to own credit risk recognized in OCI	72
Conversion into ordinary shares	(4,999,811)
Others	9
At December 31, 2020 and December 31, 2021	—

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

31. Other non-current liabilities

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Redemption liabilities (Note)	—	8,612

Note:

The Company has a legal ownership of 90% in Genetron (Wuxi) Business Management Co., Ltd. ("Genetron Wuxi") with the remaining 10% held by other investors which have injected capital of US\$1,667,000 (equivalently to approximately RMB10,821,000) in January 2021 being recognized by the Group as non-controlling interests as a result of their ownership of risks and rewards associated with their 10% interests.

Further the other investors have redemption rights upon the failure of an initial public offering of Genetron Wuxi before December 3, 2025. This event is not solely within control of the Group and thus gives rise to financial liabilities which have been recognized at present value of the redeemable amount being discounted back to RMB7,671,000 at initial subscription and subsequently measured at amortized cost.

The redeemable amount is expected to be the sum of subscriptions and annual interests thereon at 6% per annum (less accumulated dividends) up to the date of redemption notification.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
32. Cash flow information

(a) Reconciliation from loss before income tax to cash used in operations

	Year ended December 31,		
	2019	2020	2021
	RMB'000	RMB'000	RMB'000
Loss before income tax	(676,034)	(3,069,043)	(502,598)
Adjustments for:			
Depreciation on			
- property, plant and equipment	30,458	33,466	36,865
- right-of-use assets	14,784	18,277	23,821
Amortization on intangible assets	1,344	1,452	2,399
Loss allowance for trade and other receivables and contract assets	2,733	14,843	37,032
Investment income from wealth management products	(723)	(4,182)	(4,925)
Dividends from equity security	—	—	(745)
Fair value (gain)/loss - net on financial assets at FVPL	(224)	1,878	10,133
(Gain)/loss on			
- settlement of derivative financial instruments	—	(1,550)	(8,709)
- disposal of property, plant and equipment	(1,505)	—	—
- disposal of right-of-use assets	—	—	846
- disposal of subsidiaries	—	—	(2,305)
Amortization on deferred income of ADS depository	—	(2,405)	(4,373)
Finance costs/(income) - net	9,419	(22,270)	(14,061)
Share-based compensation expenses	35,884	29,951	54,144
Losses related to financial instruments with preferred rights	359,943	2,823,370	—
Others	—	(110)	—
Changes in working capital:			
- Inventories	3,719	(7,075)	(10,632)
- Contract assets	1,234	(50)	(7,277)
- Other current assets	(6,687)	7,211	5,795
- Trade receivables	(48,151)	(95,719)	(153,942)
- Other receivables and prepayments	(33)	(22,894)	(44,386)
- Amounts due from related parties	(634)	850	(383)
- Trade payables	26,633	(9,073)	23,579
- Contract liabilities	9,322	(9,772)	3,545
- Other payables and accruals	41,561	11,948	32,054
- Amounts due to related parties	—	—	(21)
Cash used in operations	<u>(196,957)</u>	<u>(300,897)</u>	<u>(524,144)</u>

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
32. Cash flow information (Continued)
(b) Reconciliation of liabilities arising from financing activities

	Financial instruments with preferred rights (Note 30) RMB'000	Amounts due to investors (Note) RMB'000	Borrowings (Note 28) RMB'000	Loans from a related party RMB'000	Lease liabilities (Note 14(a)(ii)) RMB'000	Total RMB'000
At January 1, 2019	1,320,712	—	—	—	41,418	1,362,130
Cash received	456,568	15,000	32,955	35,000	—	539,523
Cash repaid	(43,279)	—	(9,798)	(35,000)	(14,362)	(102,439)
Non-cash movements	372,333	—	—	—	17,431	389,764
At December 31, 2019	2,106,334	15,000	23,157	—	44,487	2,188,978
At January 1, 2020	2,106,334	15,000	23,157	—	44,487	2,188,978
Cash received	70,026	299,051	61,213	—	—	430,290
Cash repaid	—	(314,388)	(20,703)	—	(19,577)	(354,668)
Non-cash movements	(2,176,360)	337	409	—	34,691	(2,140,923)
At December 31, 2020	—	—	64,076	—	59,601	123,677
At January 1, 2021	—	—	64,076	—	59,601	123,677
Cash received	—	48,617	25,153	—	—	73,770
Cash repaid	—	(48,452)	(69,106)	—	(21,708)	(139,266)
Non-cash movements	—	(165)	(569)	—	16,544	15,810
At December 31, 2021	—	—	19,554	—	54,437	73,991

Note:

Upon the Reorganization certain original preferred shareholders of Genetron Health (i) subscribed preferred shares of the Company to replace their historical investment in Genetron Health; and (ii) would thereby be repaid an equivalent amount for their historical investment in Genetron Health.

As of December 31, 2019, a cash consideration of RMB15 million for the subscription of one of those investors had been received by the Company while the historical investment in Genetron Health had not yet been repaid to the investor. This balance to be repaid was non-interest bearing and settled in cash during 2020.

Similarly during 2020 and 2021, certain investors subscribed for approximately RMB299 million and RMB49 million respectively of investments in the Company and received repayments of substantially the same amounts of their historical investments in Genetron Health in the same year.

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

33. Commitments

(a) Capital commitments

	As of December 31,	
	2020 RMB'000	2021 RMB'000
Equipment and intangible assets		
- Contracted but not provided for	14,578	34,772

(b) Lease commitments

The Group leases certain office buildings under non-cancellable lease agreements.

The Group has recognized right-of-use assets for these leases, except for short-term and low-value leases (Note 14). The future minimum lease payables under such non-cancellable leases not recognized in the financial statements at each year-end date are as follows:

	As of December 31,	
	2020 RMB'000	2021 RMB'000
No later than 1 year	300	1,271
Later than 1 year but no later than 3 years	—	38
	300	1,309

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
34. Related party transactions

Parties are considered to be related if one party has the ability, directly or indirectly, to control or exercise significant influence over the other party. Parties are also considered to be related if they are subject to common control. Members of key management of the Group and their close family members are also considered as related parties.

Names of related parties	Nature of relationship
Mr. Sizhen Wang	A director of the Group
Edigene (Beijing) Inc.	A director of this entity is also a director of the Company
Hangzhou ImmuQuad Biotechnologies, LLC	A director of this entity is also a director of the Company
Juventas Cell Therapy Ltd.	Certain directors of this entity are also directors of the Group
FHP Holdings Ltd.	An entity controlled by a director of the Company

In addition to other related party transactions and balances disclosed elsewhere in these financial statements, the following is a summary of significant transactions and balances with related parties during the reported periods and at each year-end.

(a) Interests in subsidiaries of the Company are set out in Note 1.2.

(b) Significant transactions with related parties

(i) Provision of services

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Edigene (Beijing) Inc.	1,071	623	1,185
Others	588	898	56
	<u>1,659</u>	<u>1,521</u>	<u>1,241</u>

(ii) Purchase of goods and services

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Hangzhou ImmuQuad Biotechnologies, LLC	—	—	87

(iii) Loans to/from related parties

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Loans to Mr. Sizhen Wang:			
- Loans advanced	5,000	—	—
- Loans repaid	(10,525)	—	—
- Interest charged	243	—	—
- Interest paid	<u>(992)</u>	<u>—</u>	<u>—</u>

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
34. Related party transactions (Continued)

(b) Significant transactions with related parties (Continued)

(iii) Loans to/from related parties (Continued)

Loans to Mr. Sizhen Wang were unsecured, interest-bearing at 0%-4.35% per annum and repaid in 2019.

	Year ended December 31,		
	2019	2020	2021
	RMB'000	RMB'000	RMB'000
Loans from Juventas Cell Therapy Ltd.:			
- Loans advanced	35,000	—	—
- Loans repaid	(35,000)	—	—
- Interest charged	1,192	—	—
- Interest paid	(1,192)	—	—

Loans from Juventas Cell Therapy Ltd. were guaranteed by Mr. Sizhen Wang, interest-bearing at 12% per annum and repaid in 2019.

(c) Balances with related parties

(i) Trade receivables

	As of December 31,	
	2020	2021
	RMB'000	RMB'000
Edigene (Beijing) Inc.	214	597

(ii) Trade payables

	As of December 31,	
	2020	2021
	RMB'000	RMB'000
Hangzhou ImmuQuad Biotechnologies, LLC	—	3

(iii) Other payables

	As of December 31,	
	2020	2021
	RMB'000	RMB'000
FHP Holdings Ltd.	24	—

GENETRON HOLDINGS LIMITED

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

34. Related party transactions (Continued)

(d) Key management compensation

Key management includes directors and senior management personnel. The compensations paid or payable to key management for employee services are shown below:

	Year ended December 31,		
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Salaries and other short-term employee benefits	5,034	8,112	10,238
Contributions to pension plans	125	107	156
Share-based compensation expenses	17,454	15,679	15,729
	<u>22,613</u>	<u>23,898</u>	<u>26,123</u>

35. Restricted net assets and parent company only condensed financial information

The Company's ability to pay dividends is primarily dependent on the Company receiving distributions of funds from its subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by the Company's subsidiaries and VIEs incorporated in the PRC only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations.

In accordance with the PRC laws and regulations, statutory reserve funds shall be made and can only be used for specific purposes and are not distributable as cash dividends. As a result of these PRC laws and regulations that require annual appropriation of 10% of net after-tax profits to be set aside prior to payment of dividends as statutory surplus fund, unless such reserve fund reaches 50% of the entity's registered capital, VIEs and subsidiaries of VIEs are restricted in their ability to transfer a portion of their net assets to the Company. Furthermore, cash transfers from the Company's PRC subsidiaries to their parent companies outside of China are subject to PRC government control of currency conversion. Shortages in the availability of foreign currency at the time of requesting such conversion may temporarily delay the ability of the PRC subsidiaries and consolidated affiliated entities to remit sufficient foreign currency to pay dividends or other payments to the Company, or otherwise satisfy their foreign currency denominated obligations.

The Company performs a test on the restricted net assets of its consolidated subsidiaries, VIEs and subsidiaries of VIEs (the "restricted net assets") in accordance with Securities and Exchange Commission Regulation S-X Rule 4-08 (e) (3) "General Notes to Financial Statements" and concludes that the condensed financial information for the parent company is required to be presented.

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
35. Restricted net assets and parent company only condensed financial information (Continued)
(a) Balance sheets

	As of December 31,			
	2019 RMB'000 Note 2.4.3 (Restated)	2020 RMB'000 Note 2.4.3 (Restated)	2021 RMB'000	2021 US\$'000 Note 2.5(d)
ASSETS				
Non-current assets				
Interests in subsidiaries	223,464	728,152	1,138,922	178,722
Financial assets at fair value through profit or loss	—	—	25,503	4,002
Prepayments	4,172	—	19,766	3,102
Total non-current assets	227,636	728,152	1,184,191	185,826
Current assets				
Other receivables and prepayments	645	12,116	7,170	1,125
Amounts due from Group companies	4,674	6,982	6,713	1,053
Financial assets at fair value through profit or loss	—	31,953	91,562	14,368
Derivative financial instruments	—	196	—	—
Cash and cash equivalents	122,104	941,541	44,691	7,013
Total current assets	127,423	992,788	150,136	23,559
Total assets	355,059	1,720,940	1,334,327	209,385
LIABILITIES				
Non-current liabilities				
Financial instruments with preferred rights	2,106,334	—	—	—
Amounts due to Group companies	—	—	75,457	11,841
Total non-current liabilities	2,106,334	—	75,457	11,841
Current liabilities				
Other payables and accruals	26,492	27,838	51,837	8,134
Amounts due to Group companies	530	533	1,442	226
Amounts due to other related parties	34	24	—	—
Total current liabilities	27,056	28,395	53,279	8,360
Total liabilities	2,133,390	28,395	128,736	20,201
Net (liabilities)/assets	(1,778,331)	1,692,545	1,205,591	189,184
SHAREHOLDERS' (DEFICIT)/EQUITY				
Share capital	17	59	61	9
Share premium	—	6,657,562	6,711,234	1,053,139
Treasury shares	(3,578)	—	—	—
Other reserves	69,207	(24,701)	(69,091)	(10,841)
Accumulated losses	(1,843,977)	(4,940,375)	(5,436,613)	(853,123)
Total shareholders' (deficit)/equity	(1,778,331)	1,692,545	1,205,591	189,184

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
35. Restricted net assets and parent company only condensed financial information (Continued)
(b) Statements of loss

	Year ended December 31,			
	2019 RMB'000 Note 2.4.3 (Restated)	2020 RMB'000 Note 2.4.3 (Restated)	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Administrative expenses	(18,199)	(19,480)	(51,124)	(8,022)
Other income and gains - net	—	833	385	60
Finance costs - net	(6,303)	(1,230)	(479)	(75)
Financial instruments with preferred rights				
- loss on fair value changes	(208,869)	(2,823,370)	—	—
- other loss	(26,542)	—	—	—
Equity method on loss of subsidiaries	(416,121)	(225,796)	(445,020)	(69,834)
Loss before income tax	(676,034)	(3,069,043)	(496,238)	(77,871)
Income tax expense	—	—	—	—
Loss for the year	(676,034)	(3,069,043)	(496,238)	(77,871)

GENETRON HOLDINGS LIMITED
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
35. Restricted net assets and parent company only condensed financial information (Continued)
(c) Statements of cash flows

	Year ended December 31,			
	2019 RMB'000	2020 RMB'000	2021 RMB'000	2021 US\$'000 Note 2.5(d)
Cash flows from operating activities				
Cash used in operations	(10,805)	(36,241)	(35,706)	(5,603)
Net cash used in operating activities	(10,805)	(36,241)	(35,706)	(5,603)
Cash flows from investing activities				
Investment in subsidiaries	(231,062)	(1,006,010)	(886,610)	(139,129)
Purchase of wealth management products	—	(21,858)	(274,955)	(43,146)
Redemption of wealth management products	—	—	199,096	31,243
Investment income from wealth management products	—	—	1,467	230
Purchase of equity security	—	(13,721)	—	—
Purchase of other investments	—	—	(25,894)	(4,063)
Purchase of derivative financial instruments	—	(68,078)	(350,744)	(55,039)
Settlement of derivative financial instruments	—	69,628	359,165	56,360
Others	—	(294)	(66)	(10)
Net cash used in investing activities	(231,062)	(1,040,333)	(978,541)	(153,554)
Cash flows from financing activities				
Proceeds from issuance of ordinary shares	18	1,676,816	—	—
Proceeds from ADS depository	—	23,069	—	—
Proceeds from issuance of financial instruments with preferred rights	456,568	70,026	—	—
Issuance costs of financial instruments with preferred rights	(6,303)	—	—	—
Repurchase of ordinary shares	(54,479)	(4,102)	—	—
Repurchase of financial instruments with preferred rights	(43,279)	—	—	—
Proceeds from investors to the Company	15,000	299,051	48,617	7,629
Proceeds from exercise of awards	—	—	2,169	340
Proceeds from loans from Group companies	—	—	75,457	11,841
Payments in relation to listing expenses	(1,081)	(21,691)	—	—
Net cash generated from financing activities	366,444	2,043,169	126,243	19,810
Net increase/(decrease) in cash and cash equivalents	124,577	966,595	(888,004)	(139,347)
Cash and cash equivalents at beginning of year	—	122,104	941,541	147,748
Exchange differences on cash and cash equivalents	(2,473)	(147,158)	(8,846)	(1,388)
Cash and cash equivalents at end of year	122,104	941,541	44,691	7,013

(d) The Company did not have any significant guarantees, capital or other commitments as of December 31, 2020 and 2021. The VIEs and subsidiaries of VIEs did not pay any dividends to the Company for the reported periods.

List of Significant Subsidiaries and the VIEs of the Registrant and Subsidiaries of the VIEs

Significant Subsidiaries

Genetron Health (Hong Kong) Company Limited
 Genetron (Tianjin) Co., Ltd.
 Genetron Health, Inc.
 Genetron (Wuxi) Business Management Co., Ltd.

Place of Incorporation

Hong Kong
 PRC
 Delaware
 PRC

VIEs

Genetron Health (Beijing) Co., Ltd.
 Genetron (Wuxi) Biotech Co., Ltd.

Place of Incorporation

PRC
 PRC

Subsidiaries of the VIEs

Beijing Genetron Biotechnology Co., Ltd.
 Beijing Genetron Medical Laboratory Co., Ltd.
 Genetron Health (Chongqing) Co., Ltd.
 Chongqing Genetron Medical Laboratory Co., Ltd.
 Shanghai Genetron Bio-Technology Co., Ltd.
 Shanghai Genetron Medical Laboratory Co., Ltd.
 Guangzhou Genetron Bio-Technology Co., Ltd.
 Guangzhou Genetron Medical Laboratory Co., Ltd.
 Genetron (Wuxi) Medical Laboratory Co., Ltd.

Place of Incorporation

PRC
 PRC
 PRC
 PRC
 PRC
 PRC
 PRC
 PRC

Certification by the Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Sizhen Wang, certify that:

1. I have reviewed this annual report on Form 20-F of Genetron Holdings Limited (the “company”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company’s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company’s internal control over financial reporting; and
5. The company’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company’s auditors and the audit committee of the company’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company’s internal control over financial reporting.

Date:	April 29, 2022
By:	/s/ Sizhen Wang
Name:	Sizhen Wang
	Chief Executive Officer (principal
Title:	executive officer)

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Evan Ce Xu, certify that:

1. I have reviewed this annual report on Form 20-F of Genetron Holdings Limited (the “company”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company’s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company’s internal control over financial reporting; and
5. The company’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company’s auditors and the audit committee of the company’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company’s internal control over financial reporting.

Date:	April 29, 2022
By:	/s/ Evan Ce Xu
Name:	Evan Ce Xu
Title:	Chief Financial Officer (principal financial and accounting officer)

Certification by the Principal Executive Officer**Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Genetron Holdings Limited (the “Company”) on Form 20-F for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Sizhen Wang, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date:	April 29, 2022
By:	<u>/s/ Sizhen Wang</u>
Name:	Sizhen Wang
Title:	Chief Executive Officer (principal executive officer)

Certification by the Principal Financial Officer**Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Genetron Holdings Limited (the “Company”) on Form 20-F for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Evan Ce Xu, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2022

By: /s/ Evan Ce Xu

Name: Evan Ce Xu

Title: Chief Financial Officer (principal
financial and accounting officer)

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-252371) of Genetron Holdings Limited of our report dated April 29, 2022 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers Zhong Tian LLP

Beijing, the People's Republic of China

April 29, 2022

Partners:

Paul Aherne

John Cartwright

Joanne Collett

Mark Cummings

Stuart D'Addona

Nicholas Davies

Shamar Ennis

James Gaden

Thomas Granger

Kristen Kwok

Alice Molan

Thomas Pugh

Andrew Randall

Rupen Shah

Colette Wilkins

Denise Wong

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29 April 2022

Genetron Holdings Limited 泛生子基因(控股)有限公司

Walkers Corporate Limited

190 Elgin Avenue

George Town

Grand Cayman KY1-9008

Cayman Islands

Dear Sirs

Genetron Holdings Limited 泛生子基因(控股)有限公司

NASD/BLUI/G3359-H22357

We consent to the reference to our firm under the headings "Item 10.E. Additional Information—Taxation—Cayman Islands Taxation" and "Item 16.G. Corporate Governance" in Genetron Holdings Limited 泛生子基因(控股)有限公司's Annual Report on Form 20-F for the fiscal year ended 31 December 2021 (the "Annual Report"), which will be filed with the Securities and Exchange Commission (the "SEC") in the month of April 2022.

We further consent to the incorporation by reference into the Registration Statement (Form S-8 No. 333-252371) pertaining to Genetron Holdings Limited's 2019 Genetron Health Share Incentive Plan and 2019 Genetron Health Share Incentive Scheme of the summary of our opinion under the headings "Item 10.E. Additional Information—Taxation—Cayman Islands Taxation" and "Item 16.G. Corporate Governance" in the Annual Report.

We also consent to the filing with the SEC of this consent letter as an exhibit to the Annual Report.

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, or under the Securities Exchange Act of 1934, in each case, as amended, or the regulations promulgated thereunder.

Yours faithfully,

/s/ Walkers (Hong Kong)
Walkers (Hong Kong)

Walkers (Hong Kong)
滙嘉律師事務所 (香港)

15th Floor, Alexandra House, 18 Chater Road, Central, Hong Kong
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Bermuda | British Virgin Islands | Cayman Islands | Dubai | Guernsey | Hong Kong | Ireland | Jersey | London | Singapore

*England and Wales; **BVI; ***Cayman Islands; ****New South Wales (Australia); *****Victoria (Australia); *****Bermuda





April 29, 2022

To: Genetron Holdings Limited (泛生子基因(控股)有限公司)

1-2/F, Building 11, Zone 1
No.8 Life Science Parkway
Changping District, Beijing
People's Republic of China

Dear Sirs/Madams,

We hereby consent to the reference to our firm under the heading “Item 3. Key Information – D. Risk Factors - Risks Related to Our Business and Industry”, “Item 3. Key Information – D. Risk Factors - Risks Related to Our Corporate Structure”, “Item 4. Information on the Company – C. Organizational Structure” and “Item 10. Additional Information – E. Taxation” in Genetron Holdings Limited’s annual report on Form 20-F for the fiscal year ended December 31, 2021, which will be filed by Genetron Holdings Limited in April 2022 with the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and further consent to the incorporation by reference of the summaries of our opinions that appear in the annual report on Form 20-F into the Registration Statements (No. 333-252371) on Form S-8.

We also consent to the filing with the Securities and Exchange Commission of this consent letter as an exhibit to the annual report on Form 20-F for the fiscal year ended December 31, 2021. In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, or under the Securities Exchange Act of 1934, in each case, as amended, or the regulations promulgated thereunder.

Yours Sincerely,

/s/ SHIHUI PARTNERS
SHIHUI PARTNERS
