Cryofocus Medtech (Shanghai) Co., Ltd.
康灃生物科技(上海)股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 6922)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2023

FINANCIAL HIGHLIGHTS

	Year ended December 31, 2023 *RMB'000*	Year ended December 31, 2022 *RMB'000*	**Change year-on-year**
Revenue	**40,950**	27,149	50.8%
Gross profit	**31,052**	19,362	60.4%
Loss for the year	**(105,746)**	(118,316)	-10.6%

BUSINESS HIGHLIGHTS

During the Reporting Period and up to the date of this announcement, we have made significant progress in all aspects of the business. In particular, we have made the following progress with respect to our product pipeline and business operation:

- We received NMPA approval for our Atrial Fibrillation Cryoablation System in December 2023.
- We passed the GMP examination for our Atrial Fibrillation Cryoablation System in January 2024.
- We received marketing approval for the Cryoadhesion System in January 2024, after securing NMPA approval for the accompanying cryotherapy equipment in December 2023 and the disposable cryoprobe in January 2024.
- The patients enrollment for the confirmatory clinical trial of our Malignant Stenosis Cryoablation System has been completed.
- Our Asthma Cryoablation System and our COPD Cryospray System entered into the confirmatory clinical trial phase in March 2023.
- Our Benign Stenosis Cryoablation System entered into the confirmatory clinical trial phase in January 2024.
- Our Peri-Pulmonary Nodule Cryoablation System entered into the feasibility clinical trial phase in August 2023.

The Board is pleased to announce the consolidated annual results of the Group for the year ended December 31, 2023, together with the comparative figures for the year ended December 31, 2022.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Year ended December 31, 2023

	Notes	**2023** ***RMB'000***	2022 *RMB'000*
REVENUE	*4*	**40,950**	27,149
Cost of sales		**(9,898)**	(7,787)
Gross profit		**31,052**	19,362
Other income and gains	*4*	**14,959**	11,372
Research and development expenses		**(76,129)**	(59,933)
Selling and distribution expenses		**(5,692)**	(4,559)
Administrative expenses		**(69,003)**	(83,766)
Other expenses		**(282)**	(205)
Finance costs		**(651)**	(587)
LOSS BEFORE TAX		**(105,746)**	(118,316)
Income tax expenses	*5*	**–**	–
LOSS FOR THE YEAR		**(105,746)**	(118,316)
Attributable to:			
Owners of the parent		**(97,486)**	(112,222)
Non-controlling interests		**(8,260)**	(6,094)
		(105,746)	(118,316)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted			
For loss for the year	*7*	**RMB(0.41)**	RMB(0.49)

	2023 *RMB'000*	2022 *RMB'000*
LOSS FOR THE YEAR	**(105,746)**	(118,316)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**(41)**	18
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	**(41)**	18
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(105,787)**	(118,298)
Attributable to:		
Owners of the parent	**(97,527)**	(112,204)
Non-controlling interests	**(8,260)**	(6,094)
	(105,787)	(118,298)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

December 31, 2023

	Notes	**2023** ***RMB'000***	2022 *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**40,165**	31,081
Right-of-use assets		**11,112**	10,680
Other intangible assets		**22**	40
Other non-current assets		**11,607**	7,854
Total non-current assets		**62,906**	49,655
CURRENT ASSETS			
Inventories		**24,354**	19,928
Trade receivables	*8*	**–**	–
Prepayments, other receivables and other assets	*9*	**22,088**	17,858
Restricted cash		**71**	–
Cash and cash equivalents		**103,402**	226,422
Total current assets		**149,915**	264,208
CURRENT LIABILITIES			
Trade payables	*10*	**906**	1,763
Other payables and accruals	*11*	**25,637**	37,275
Lease liabilities		**3,247**	3,432
Contract liabilities		**992**	3,264
Total current liabilities		**30,782**	45,734
NET CURRENT ASSETS		**119,133**	218,474
TOTAL ASSETS LESS CURRENT LIABILITIES		**182,039**	268,129
NON-CURRENT LIABILITIES			
Lease liabilities		**7,764**	7,939
Deferred income		**815**	801
Total non-current liabilities		**8,579**	8,740
NET ASSETS		**173,460**	259,389

	Notes	2023 *RMB'000*	2022 *RMB'000*
EQUITY			
Equity attributable to owners of the parent			
Share capital		**239,110**	239,110
Reserves		**(77,645)**	24
		161,465	239,134
Non-controlling interests		**11,995**	20,255
Total equity		**173,460**	259,389

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended December 31, 2023

1. CORPORATE AND GROUP INFORMATION

Cryofocus Medtech (Shanghai) Co., Ltd. ("the **Company**") is a joint stock company with limited liability established in the People's Republic of China ("**PRC**"). The registered office of the Company is located at Building 15, Lane 3399, Kangxin Road, Pudong New District, Shanghai, the PRC.

During the year, the Group was principally engaged in the following activities:

- research and development, manufacture and sale of cryoablation minimally-invasive interventional treatment technology and related medical products
- manufacture and sale of minimally-invasive surgical consumables

The Company was listed on the Main Board of The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") on December 30, 2022.

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with Hong Kong Financial Reporting Standards ("**HKFRSs**") (which include all Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards ("**HKASs**") and Interpretations) issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**"), and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for financial assets at fair value through profit or loss, which have been measured at fair value. These financial statements are presented in RMB and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following new and revised HKFRSs for the first time for the current year's financial statements.

HKFRS 17	*Insurance Contracts*
Amendments to HKAS 1 and HKFRS Practice Statement 2	*Disclosure of Accounting Policies*
Amendments to HKAS 8	*Definition of Accounting Estimates*
Amendments to HKAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*
Amendments to HKAS 12	*International Tax Reform – Pillar Two Model Rules*

The nature and the impact of the revised HKFRSs that are applicable to the Group are described below:

(a) Amendments to HKAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to HKFRS Practice Statement 2 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has disclosed the material accounting policy information in note 2 to the financial statements. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Group's financial statements.

(b) Amendments to HKAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. Since the Group's approach and policy align with the amendments, the amendments had no impact on the Group's financial statements.

(c) Amendments to HKAS 12 *Deferred Tax related to Assets and Liabilities arising from a Single Transaction* narrow the scope of the initial recognition exception in HKAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions.

The Group did not recognise a deferred tax asset or a deferred tax liability for temporary differences, the amendments had no impact on the Group's financial statements.

(d) Amendments to HKAS 12 *International Tax Reform – Pillar Two Model Rules* introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Group.

2.3 ISSUED BUT NOT YET EFFECTIVE HONG KONG FINANCIAL REPORTING STANDARDS

The Group has not applied the following revised HKFRSs, that have been issued but are not yet effective, in these financial statements. The Group intends to apply these revised HKFRSs, if applicable, when they become effective.

Amendments to HKFRS 10 and HKAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture* [3]
Amendments to HKFRS 16	*Lease Liability in a Sale and Leaseback* [1]
Amendments to HKAS 1	*Classification of Liabilities as Current or Non-current* (the "**2020 Amendments**") [1, 4]
Amendments to HKAS 1	*Non-current Liabilities with Covenants* (the "**2022 Amendments**") [1, 4]
Amendments to HKAS 7 and HKFRS 7	*Supplier Finance Arrangements* [1]
Amendments to HKAS 21	*Lack of Exchangeability* [2]

[1] Effective for annual periods beginning on or after January 1, 2024

[2] Effective for annual periods beginning on or after January 1, 2025

[3] No mandatory effective date yet determined but available for adoption

[4] As a consequence of the 2020 Amendments and 2022 Amendments, Hong Kong Interpretation 5 *Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause* was revised to align the corresponding wording with no change in conclusion

Further information about those HKFRSs that are expected to be applicable to the Group is described below.

Amendments to HKFRS 10 and HKAS 28 address an inconsistency between the requirements in HKFRS 10 and in HKAS 28 in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss resulting from a downstream transaction when the sale or contribution of assets constitutes a business. For a transaction involving assets that do not constitute a business, a gain or loss resulting from the transaction is recognised in the investor's profit or loss only to the extent of the unrelated investor's interest in that associate or joint venture. The amendments are to be applied prospectively. The previous mandatory effective date of amendments to HKFRS 10 and HKAS 28 was removed by the HKICPA. However, the amendments are available for adoption now.

Amendments to HKFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognise any amount of the gain or loss that relates to the right of use it retains. The amendments are effective for annual periods beginning on or after January 1, 2024 and shall be applied retrospectively to sale and leaseback transactions entered into after the date of initial application of HKFRS 16 (i.e., January 1, 2019). Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

The 2020 Amendments clarify the requirements for classifying liabilities as current or non-current, including what is meant by a right to defer settlement and that a right to defer must exist at the end of the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement. The amendments also clarify that a liability can be settled in its own equity instruments, and that only if a conversion option in a convertible liability is itself accounted for as an equity instrument would the terms of a liability not impact its classification. The 2022 Amendments further clarify that, among covenants of a liability arising from a loan arrangement, only those with which an entity must comply on or before the reporting date affect the classification of that liability as current or non-current. Additional disclosures are required for non-current liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period. The amendments shall be applied retrospectively with early application permitted. An entity that applies the 2020 Amendments early is required to apply simultaneously the 2022 Amendments, and vice versa. The Group is currently assessing the impact of the amendments and whether existing loan agreements may require revision. Based on a preliminary assessment, the amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to HKAS 7 and HKFRS 7 clarify the characteristics of supplier finance arrangements and require additional disclosure of such arrangements. The disclosure requirements in the amendments are intended to assist users of financial statements in understanding the effects of supplier finance arrangements on an entity's liabilities, cash flows and exposure to liquidity risk. Earlier application of the amendments is permitted. The amendments provide certain transition reliefs regarding comparative information, quantitative information as at the beginning of the annual reporting period and interim disclosures. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to HKAS 21 specify how an entity shall assess whether a currency is exchangeable into another currency and how it shall estimate a spot exchange rate at a measurement date when exchangeability is lacking.

The amendments require disclosures of information that enable users of financial statements to understand the impact of a currency not being exchangeable. Earlier application is permitted. When applying the amendments, an entity cannot restate comparative information. Any cumulative effect of initially applying the amendments shall be recognised as an adjustment to the opening balance of retained profits or to the cumulative amount of translation differences accumulated in a separate component of equity, where appropriate, at the date of initial application. The amendments are not expected to have any significant impact on the Group's financial statements.

3. OPERATING SEGMENT INFORMATION

Operating segment information

The Group is engaged in research and development of medical consumables and devices, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group's senior management for purposes of resource allocation and performance assessment. Therefore, no further operating segment analysis thereof is presented.

Geographical information

Since nearly all of the Group's revenue was generated from sale of medical consumables and devices in Chinese Mainland and nearly all of the Group's non-current assets were located in Chinese Mainland, no further geographical segment information in accordance with HKFRS 8 *Operating Segments* is presented.

Information about major customers

Revenue of approximately RMB5,752,000 (2022: RMB2,746,000) was derived from sale of medical consumables and devices to a single customer, including sales to a group of entities which are known to be under common control with that customer.

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2023	2022
	RMB'000	*RMB'000*
Revenue from contracts with customers		
Sale of medical devices and consumables	**40,950**	27,149

(a) Disaggregated revenue information

For the year ended December 31, 2023

	2023	2022
	RMB'000	*RMB'000*
Goods transferred at a point in time	**40,950**	27,149

The following table shows the amount of revenue recognised in the current reporting period that was included in the contract liabilities at the beginning of the reporting period and recognised from performance obligations satisfied in previous periods:

	2023	2022
	RMB'000	*RMB'000*
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Medical consumables	**3,160**	1,306

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sales of medical consumables and devices

The performance obligation is satisfied upon delivery and inspection of the medical consumables and devices, where payment in advance is normally required.

An analysis of other income and gains is as follows:

	2023	2022
	RMB'000	*RMB'000*
Other income		
Government grants	**12,025**	7,542
Bank interest income	**1,223**	724
Investment income	**–**	463
Others	**11**	21
	13,259	8,750
Gains		
Foreign exchange differences, net	**1,700**	2,622
	1,700	2,622
	14,959	11,372

5. INCOME TAX EXPENSES

The Group is subject to income tax on an entity basis on profits arising in or derived from the tax jurisdictions in which members of the Group are domiciled and operate. The Group's principal applicable taxes and tax rates are as follows:

Chinese Mainland

No provision for Chinese Mainland income tax has been provided for at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the related regulations (the "**CIT Law**"), as the Group's PRC entities have no estimated assessable profits. One of the subsidiaries of the Group was recognised as a High and New Technology Enterprise and was entitled to a preferential tax rate of 15% during the year.

United States of America

The subsidiary incorporated in California, the United States is subject to statutory United States federal corporate income tax at a rate of 21%. It was also subject to the state income tax in California during the year. No provisions for federal corporate income tax and the state income tax have been provided as the subsidiary was loss-making during the year.

A reconciliation of the tax expense applicable to profit before tax at the statutory rate for the jurisdiction in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rates, and a reconciliation of the applicable rates (i.e., the statutory tax rates) to the effective tax rates, are as follows:

	2023	2022
	RMB'000	*RMB'000*
Loss before tax	**(105,746)**	(118,316)
Tax at the statutory tax rate (25%)	**(26,436)**	(29,579)
Different tax rate enacted by local authority	**1,980**	2,574
Additional deductible allowance for qualified research and development expenses	**(12,206)**	(8,192)
Expenses not deductible for tax	**984**	429
Tax losses not recognised	**35,678**	34,768
Tax charge at the Group's effective rate	**–**	–

The Group has accumulated tax losses in Chinese Mainland of RMB654,790,000 as of December 31, 2023 (2022: RMB574,129,000), that will expire in one to ten years for offsetting against future taxable profits of the companies in which the losses arose.

The Group also has accumulated tax losses in the United States of America of RMB6,824,000 as of December 31, 2023 (2022: RMB5,243,000), that will be carried forward indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

6. DIVIDENDS

No dividend was paid or declared by the Company during the year (2022: Nil).

7. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 239,110,000 (2022: 228,030,438) in issue during the year, as adjusted to reflect the rights issue during the year. The weighted average number of ordinary shares in issue before the conversion from a limited liability company into a joint stock company was determined by assuming that the paid-in capital had been fully converted into share capital upon transformation into a joint stock company in July 2021.

No adjustment has been made to the basic loss per share amounts presented for the years ended December 31, 2023 and 2022 in respect of a dilution as the impact of the share options outstanding has an anti-dilutive effect on the basic loss per share amount presented.

8. TRADE RECEIVABLES

	2023	2022
	RMB'000	*RMB'000*
Trade receivables	**74**	74
Impairment	**(74)**	(74)
	–	–

The Group's trading terms with its customers are mainly on advance payments from the customers, except for some customers, who are of lower credit risk evaluated by senior management, and the Group seeks to maintain strict control over its outstanding receivables to minimize credit risk. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	2023	2022
	RMB'000	*RMB'000*
Over 3 years	**–**	–

The movements in the loss allowance for impairment of trade receivables are as follows:

	2023	2022
	RMB'000	*RMB'000*
At beginning of year	**74**	74
Impairment losses, net	**–**	–
At end of year	**74**	74

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions.

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

	As of December 31, 2023		
	Expected credit loss rate	**Gross carrying amount** ***RMB'000***	**Expected credit losses** ***RMB'000***
Over 3 years	**100.00%***	**74**	**74**

	As of December 31, 2022		
	Expected credit loss rate	Gross carrying amount *RMB'000*	Expected credit losses *RMB'000*
Over 3 years	100.00%*	74	74

* The Group sold medical products to a third party in 2018, and confirmed a trade receivable of RMB74,000 on December 31, 2018. Management conducted a credit risk assessment on the trade receivable, and believed that the amount was credit-impaired and the trade receivable was not expected to be settled. Therefore, the Group made a provision for impairment of a trade receivable with the expected credit loss rate of 100%. During the year, except for the above trade receivable, the Group had no other trade receivables.

9. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	2023	2022
	RMB'000	*RMB'000*
Amounts due from related parties	**131**	84
Prepayment to suppliers	**18,137**	13,690
Employee reserve fund	**2,255**	1,672
Deposits	**1,053**	1,918
Others	**1,132**	845
	22,708	18,209
Impairment loss for other receivables	**(620)**	(351)
	22,088	17,858

The movements in provision for impairment of other receivables are as follows:

	2023	2022
	RMB'000	*RMB'000*
At beginning of year	**351**	146
Impairment losses, net	**269**	205
At end of year	**620**	351

10. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of the reporting period, based on the invoice dates, is as follows:

	2023	2022
	RMB'000	*RMB'000*
Within 1 year	**906**	1,763

The trade payables are non-interest-bearing and are normally settled within one to three months.

11. OTHER PAYABLES AND ACCRUALS

	2023	2022
	RMB'000	*RMB'000*
Amounts due to related parties	**243**	104
Payroll and welfare payable	**17,301**	16,351
Other taxes and surcharges payable	**2,069**	1,977
Accrued expenses	**4,380**	18,420
Payable for capital expenditure	**1,114**	–
Other payables	**530**	423
	25,637	37,275

Other payables and accruals are unsecured, non-interest-bearing and repayable on demand.

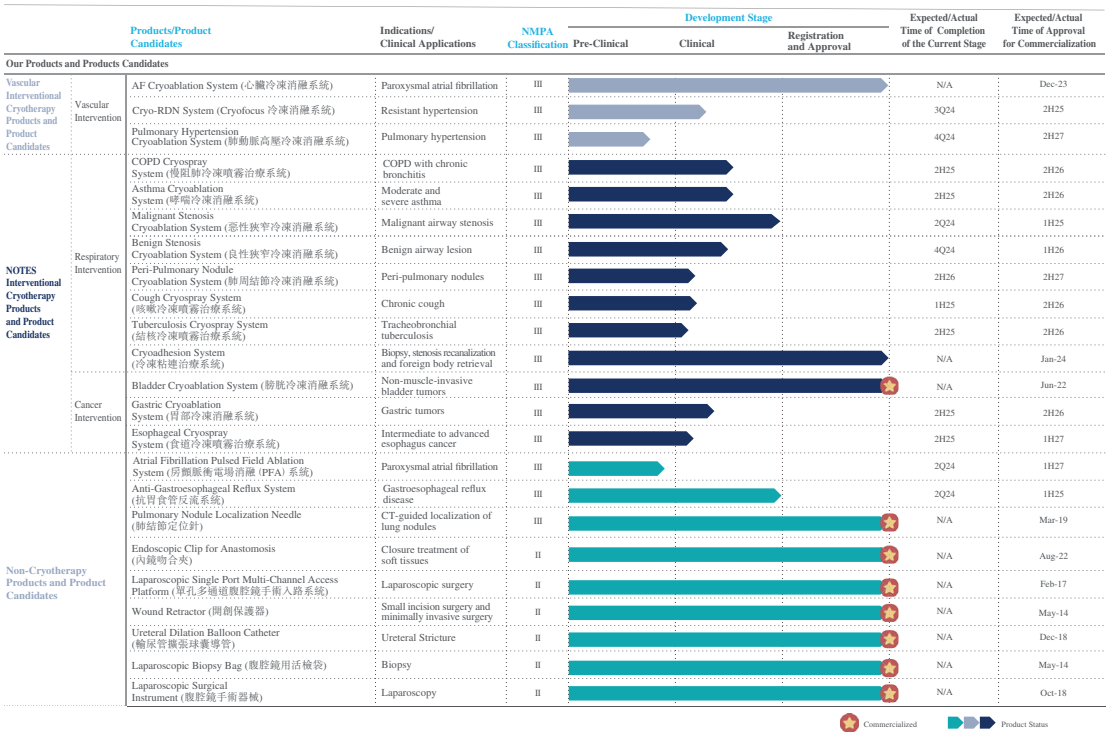
I. BUSINESS REVIEW

Overview

We are an innovative medical device company in China with a main focus on the field of minimally-invasive interventional cryotherapy. We use liquid nitrogen as the main cryogenic source for cryotherapy systems by leveraging our unique liquid nitrogen cryoablation technology and advanced flexible catheter technology. Since our inception in 2013, we have developed a comprehensive product portfolio mainly focusing on two therapeutic areas: (i) vascular interventional therapy for the treatment of atrial fibrillation, hypertension and other cardiovascular diseases; and (ii) natural orifice transluminal endoscopic surgery, or NOTES, for the treatment of urinary, respiratory, and digestive diseases (e.g., bladder cancer, chronic obstructive pulmonary disease, asthma, airway stenosis, gastric cancer, and esophageal cancer). We believe our competitive advantage, technologies and product pipeline have helped us establish high entry barriers difficult for our competitors to surpass.

Products and Pipeline

We have developed a comprehensive product portfolio including 14 cryotherapy products and product candidates with a main focus on vascular intervention and NOTES, as well as nine additional non-cryotherapy products and product candidates. We have commercialized eight products as at the date of this announcement. The following diagram summarizes the status of our products and product candidates as at the date of this announcement.



Our Products and Product Candidates

Vascular Interventional Cryotherapy Products and Product Candidates

Vascular Intervention

1. AF Cryoablation System

Our Atrial Fibrillation Cryoablation System (心臟冷凍消融系統) ("**AF Cryoablation System**") is a self-developed cryoablation system indicated for the treatment of paroxysmal atrial fibrillation. The AF Cryoablation System treats atrial fibrillation by freezing and destroying abnormal heart tissues that create irregular heartbeats in a minimally invasive procedure.

We initiated the clinical trial for the AF Cryoablation System in October 2019. We submitted the registration application for our AF Cryoablation System to the NMPA in July 2022, and have received the NMPA approval for the AF Cryoablation System in December 2023. Further, we have passed the Good Manufacturing Practice ("**GMP**") examination conducted by the Shanghai Medical Products Administration for the AF Cryoablation System in January 2024.

2. Cryo-RDN System

Our Cryofocus Renal Denervation System (Cryofocus 冷凍消融系統) ("**Cryo-RDN System**") is a self-developed cryoablation system designed for the treatment of hypertension. Renal denervation is a minimally-invasive procedure intended to deliver energy to overactive nerves in the kidney, which is a cause of hypertension, so as to decrease their activity and treat hypertension. Our Cryo-RDN System delivers liquid nitrogen to the target area of the renal artery to perform circumferential ablation, which damages nerve tissues through the formation and rewarming of ice balls, thus achieving the treatment of hypertension.

We aim to make this product candidate the world's first cryoablation product that specifically focuses on the treatment of hypertension. In December 2022, the Cryo-RDN System was granted designation as a "Breakthrough Device" by the FDA. We are currently conducting a confirmatory clinical trial of the Cryo-RDN System, and we expect to obtain approval from the NMPA in the second half of 2025.

3. Pulmonary Hypertension Cryoablation System

Our Pulmonary Hypertension Cryoablation System (肺動脈高壓冷凍消融系統) ("**PH Cryoablation System**") is a self-developed cryoablation system designed for treating pulmonary hypertension. It employs a balloon catheter to perform circumferential cryoablation on the sympathetic nerve of pulmonary artery, effectively isolating the sympathetic nerve signaling and thus treating pulmonary hypertension.

Our PH Cryoablation System is currently in the stage of pre-clinical study and we expect to obtain approval from the NMPA in the second half of 2027.

NOTES Interventional Cryotherapy Products and Product Candidates

Respiratory Intervention

1. COPD Cryospray System

Our COPD Cryospray System (慢阻肺冷凍噴霧治療系統) is a spray cryotherapy system developed by the Company, which is indicated to perform cryotherapy for patients suffering from COPD with chronic bronchitis. Our COPD Cryospray System ablates and deactivates the diseased airway mucosal epithelium by spraying liquid nitrogen under the bronchoscope to achieve therapeutic effect.

Our COPD Cryospray System entered into the confirmatory clinical trial phase in March 2023. We expect to submit the product registration submission to the NMPA in the second half of 2025 and to obtain approval from the NMPA in the second half of 2026.

2. Asthma Cryoablation System

Our Asthma Cryoablation System (哮喘冷凍消融系統) is a self-developed cryoablation system for treating moderate and severe asthma.

The Asthma Cryoablation System consists of a cryotherapy equipment and an airway cryoablation catheter. During the procedure, the Asthma Cryoablation System destroys the vagus nerve in the lungs through cryoablation, reducing the release of over-activated acetylcholine that is a cause of asthma, and decreasing mucus secretion, thus achieving the effect of treating asthma.

Our Asthma Cryoablation System entered into the confirmatory clinical trial phase in March 2023. We expect to submit the product registration submission to the NMPA in the second half of 2025 and to obtain approval from the NMPA in the second half of 2026.

3. Malignant Stenosis Cryoablation System

Our Malignant Stenosis Cryoablation System (惡性狹窄冷凍消融系統) is a self-developed cryoablation system indicated to ablate malignant airway tumor tissue and reduce the frequency of airway restenosis.

The Malignant Stenosis Cryoablation System consists of a cryotherapy equipment and an airway cryoablation catheter. During the procedure, the Malignant Stenosis Cryoablation System ablates tumor cells in the lumen and luminal wall of the trachea with the ultra-low temperature generated by the cryoablation system, and then further destroys tumor cells through rewarming. The cryoablation balloon allows for more complete ablation of malignant tumors on a larger scale and delays restenosis time.

Our Malignant Stenosis Cryoablation System is currently in the confirmatory clinical trial phase and for which the patients enrollment has been completed. We expect to submit the product registration submission to the NMPA in the second quarter of 2024 and to obtain approval from the NMPA in the first half of 2025.

4. Benign Stenosis Cryoablation System

Our Benign Stenosis Cryoablation System (良性狹窄冷凍消融系統) is a self-developed cryoablation system based on liquid nitrogen for ablating benign airway stenosis lesion. This product candidate can dilate and shape the airway stenosis with the balloon dilation and perform cryoablation treatment and reduce the frequency of airway restenosis.

Our Benign Stenosis Cryoablation System entered into the confirmatory clinical trial phase in January 2024. We expect to submit the product registration submission to the NMPA in the fourth quarter of 2024 and to obtain approval from the NMPA in the first half of 2026.

5. Peri-Pulmonary Nodule Cryoablation System

Our Peri-Pulmonary Nodule Cryoablation System (肺周結節冷凍消融系統) is a self-developed cryoablation system for treating peri-pulmonary nodules. Our Peri-Pulmonary Nodule Cryoablation System consists of a cryotherapy equipment and an airway cryoablation catheter. During the procedure, the Peri-Pulmonary Nodule Cryoablation System delivers the cryoablation balloon to the target site through the bronchoscope, the ultra-low temperature from liquid nitrogen in the catheter leads to the rapid formation of ice spheres inside the tumor, which results in the formation of ice crystals inside and outside the tumor cells, thus destroying the tumor cells. The Peri-Pulmonary Nodule Cryoablation System adopts a flexible catheter and trans-airway access treatment modality, which can greatly reduce the chance of pneumothorax, hemoptysis and other complications.

Our Peri-Pulmonary Nodule Cryoablation System entered into the feasibility clinical trial phase in August 2023. We expect to submit the product registration submission to the NMPA in the second half of 2026, and to receive the NMPA approval for this product in the second half of 2027.

6. Cough Cryospray System

Our Cough Cryospray System (咳嗽冷凍噴霧治療系統) is a self-developed cryoablation system for treating chronic cough. It achieves therapeutic effect by ablating visible lesions in the airway.

Our Cough Cryospray System is currently in the feasibility clinical trial phase. We expect to submit the product registration submission to the NMPA in the first half of 2025 and to obtain approval from the NMPA in the second half of 2026.

7. Tuberculosis Cryospray System

Our Tuberculosis Cryospray System (結核冷凍噴霧治療系統) is a spray cryotherapy system developed by the Company for treating tracheobronchial tuberculosis. It achieves therapeutic effect by ablating visible lesions in the airway.

Our Tuberculosis Cryospray System is currently in the feasibility clinical trial phase. We expect to submit the product registration submission to the NMPA in the second half of 2025 and to obtain approval from the NMPA in the second half of 2026.

8. Cryoadhesion System

Our Cryoadhesion System (冷凍粘連治療系統) is a cryoadhesion device used for biopsy, stenosis recanalization and foreign body retrieval. It employs subcritical refrigeration technology (亞臨界製冷技術) and heat transfer with controlled pressure technology (控壓傳熱技術) for rapid freezing and adhesion.

This product candidate consists of a disposable cryoprobe (一次性使用冷凍探頭) and an accompanying cryotherapy equipment (冷凍治療設備). During the operation, the cryoprobe is connected to the cryotherapy equipment, and the distal end of the disposable cryoprobe is brought into contact with the target tissue or foreign body under endoscopic guidance for cryoadhesion to achieve tissue biopsy, stenosis recanalization and foreign body removal.

We received marketing approval for the Cryoadhesion System in January 2024, after securing NMPA approval for the accompanying cryotherapy equipment in December 2023 and the disposable cryoprobe in January 2024.

Cancer Intervention

1. Bladder Cryoablation System

Our Bladder Cryoablation System (膀胱冷凍消融系統) is a self-developed cryoablation system for the treatment of bladder tumors. This product employs liquid nitrogen to perform efficient cryoballoon ablation on target tissue, and similar to Bacillus Calmette-Guerin perfusion or chemotherapy, this product is indicated for use in conjunction with transurethral resection of bladder tumor surgeries to reduce tumor residuals for patients suffering from non-muscle-invasive bladder cancer.

We initiated the clinical trial for the Bladder Cryoablation System in November 2017, and received the NMPA approval for the Bladder Cryoablation System in June 2022. We commercialized our Bladder Cryoablation System in China in December 2022.

2. Gastric Cryoablation System

Our Gastric Cryoablation System (胃部冷凍消融系統) is a self-developed cryoablation system indicated for performing cryoablation on gastric tumors to treat gastric cancer.

The Gastric Cryoablation System consists of a cryotherapy equipment (冷凍治療設備) and a cryotherapy catheter (冷凍治療導管). During the procedure, the cryoablation equipment provides a stable delivery of liquid nitrogen and the catheter can pass through an electronic gastroscope into the stomach. The distal end of the catheter is connected to a pre-folded balloon, which can expand after passing through the electronic gastroscope to contact the target gastric mucosa, creating an ultra-low temperature at the balloon through the stable delivery of liquid nitrogen within the balloon to destroy target cells. When reaching the set freezing time, the system stops freezing process, and starts rewarming cycle which further destroys the target cells.

Our Gastric Cryoablation System is currently in the feasibility clinical trial phase. We expect to submit the product registration submission to the NMPA in the second half of 2025 and to obtain approval from the NMPA in the second half of 2026.

3. Esophageal Cryospray System

Our Esophageal Cryospray System (食道冷凍噴霧治療系統) is used to perform endoscopic spray cryotherapy on patients with intermediate to advanced esophagus cancer to reduce the size of the tumor, alleviate the symptoms of dysphagia and improve their quality of life.

Patients with intermediate to advanced esophagus cancer may have trouble swallowing due to esophageal stricture as a result of tumor occupancy. Our Esophageal Cryospray System can spray liquid nitrogen directly on the surface of the tumor to destroy the tumor cells, thus reducing the volume of the tumor, alleviating the patient's dysphagia, and improving the quality of life.

Our Esophageal Cryospray System is currently in the feasibility clinical trial phase. We expect to submit the product registration submission to the NMPA in the second half of 2025 and to obtain approval from the NMPA in the first half of 2027.

Non-Cryotherapy Products and Product Candidates

1. Pulmonary Nodule Localization Needle

Our Pulmonary Nodule Localization Needle (肺結節定位針), also known as the Disposable Pulmonary Nodule Localization Needle, is a single-use localization needle indicated for CT-guided localization of lung nodules in patients with lung nodules prior to undergoing thoracoscopic surgery. Our Pulmonary Nodule Localization Needle adopts a combination of multi-hook localization and flexible wire, which greatly reduces the risk of dislocation after localization to ensure safe and effective resection of pulmonary nodules during surgery.

Our Pulmonary Nodule Localization Needle received the NMPA registration certificate in March 2019 and was subsequently commercialized in China in May 2019, and obtained CE Marking in January 2019. As at the date of this announcement, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for our Pulmonary Nodule Localization Needle.

2. Endoscopic Clip for Anastomosis

Our Endoscopic Clip for Anastomosis (內鏡吻合夾) is a self-developed anastomotic device for closure (閉合治療) of soft tissue in digestive tract. It is indicated for the closure treatment of bleeding, perforation, and tissue defects in digestive tract, and in particular, is suitable for treating perforation in gastrointestinal endoscopic surgery and endoscopic full-thickness closure (全層內鏡閉合) after NOTES. Its addressable patients primarily include the patients with acute gastrointestinal bleeding, ulcerative or medically induced perforations, or those undergoing endoscopic tissue removal procedures. This product offers various benefits, such as its large clamping scope and strong clamping force, and it is detachable to facilitate the clip removal and avoid secondary damage to the tissue. This product is one of the over-the-scope clips approved for commercialization in China.

We initiated the clinical trial for the Endoscopic Clip for Anastomosis in June 2020, and received the approval for this product in August 2022. We commercialized this product in October 2022. As at the date of this announcement, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for the Endoscopic Clip for Anastomosis.

3. Laparoscopic Single Port Multi-Channel Access Platform

Our Laparoscopic Single Port Multi-Channel Access Platform (單孔多通道腹腔鏡手術入路系統), also known as the Disposable Multi-Channel Laparoscopic Access Platform, is a self-developed system used in laparoscopic surgery as a channel for the endoscope, instruments and hands during surgery. It is applicable for single incision laparoscopic surgery, NOTES, reduced-port laparoscopic surgery, or hand-assisted laparoscopic surgery.

Our Laparoscopic Single Port Multi-Channel Access Platform received the registration certificate in February 2017 and was subsequently commercialized in China in April 2017, and obtained CE Marking in January 2019. As at the date of this announcement, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for our Laparoscopic Single Port Multi-Channel Access Platform.

4. Atrial Fibrillation Pulsed Field Ablation System

Our Atrial Fibrillation Pulsed Field Ablation System (房顫脈衝電場消融(PFA)系統) ("**AF PFA System**") is indicated for use in the interventional treatment of paroxysmal atrial fibrillation. It destroys myocardial tissue with high voltage electrical impulses to achieve electrical isolation of the pulmonary vein vestibule, resulting in the therapeutic effect.

Our Atrial Fibrillation Pulsed Field Ablation System is currently in the stage of pre-clinical study and is expected to be approved by the NMPA in the first half of 2027.

5. Anti-Gastroesophageal Reflux System

Our self-developed Anti-Gastroesophageal Reflux System (抗胃食管反流系統) is a surgical device indicated for treating gastroesophageal reflux disease ("**GERD**") in the magnetic sphincter augmentation procedure. The magnetic sphincter augmentation procedure is designed to treat GERD by increasing the tension of the lower esophageal sphincter to achieve anti-reflux effect.

Our Anti-Gastroesophageal Reflux System is currently in the confirmatory clinical trial phase. We expect to submit the product registration submission to the NMPA in the second quarter of 2024 and to obtain approval from the NMPA in the first half of 2025.

6. Other Non-Cryotherapy Products

Our non-cryoablation products also include our Wound Retractor (開創保護器), Ureteral Dilation Balloon Catheter (輸尿管擴張球囊導管), Laparoscopic Biopsy Bag (腹腔鏡用活檢袋) (also known as Endoscopic Biopsy Bag), and Laparoscopic Surgical Instrument (腹腔鏡手術器械). They are all single-use medical consumables. As at the date of this announcement, all such non-cryoablation products have been commercialized and there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals for these non-cryoablation products.

WE CANNOT GUARANTEE THE FUTURE PROSPECTS OF OUR CORE PRODUCTS AND WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR OTHER PRODUCT CANDIDATES.

Research and Development

We have established a dedicated product development team led by industry experts with extensive experience in the medical device industry or in the field of engineering research and development. As of December 31, 2023, our product development team consisted of an in-house research and development team of 99 employees and a clinical operation team of 38 employees (including certain management members undertaking product development functions). We have also developed relationships with industry leaders, including scientists, physicians and industry practitioners, giving us a thorough understanding of the clinical needs and demands of patients and physicians.

We have built a comprehensive intellectual property portfolio in China and overseas to protect our technologies, including our core liquid nitrogen cryoablation technology, flexible catheter technology and other key technologies. As of December 31, 2023, we owned 147 patents and 46 patent applications in China and overseas.

Production

In 2023, we manufactured, assembled and tested our products at our two production facilities, one being a leased property in Ningbo, Zhejiang Province and the other being a self-owned property in Shanghai, with a total gross floor area of over 12,800 square meters. We produce commercial products, mainly including our Core Products (as defined under the Listing Rules) as well as other commercialized products, including our Pulmonary Nodule Localization Needle and Laparoscopic Single Port Multi-Channel Access Platform, and also produce, assemble and test sample products related to NOTES at our production facility in Ningbo. We produce, assemble and test sample products related to vascular intervention for product development at our facility in Shanghai.

Future and Outlook

Our mission is to become a global medical device platform in the field of minimally-invasive interventional cryotherapy, bringing benefits to patients and physicians worldwide with our cryotherapy technology. We plan to implement the following strategies to achieve our goal:

- Rapidly advance the clinical development and commercialization of our product candidates;

- Further expand our product portfolio leveraging technology platforms and continue to focus on minimally-invasive interventional cryotherapy;

- Continue to research and develop various underlying and supporting technologies; and

- Selectively expand our worldwide footprint.

II. FINANCIAL REVIEW

Revenue

Our revenue increased by RMB13.9 million, or 50.8%, from RMB27.1 million for the year ended December 31, 2022 to RMB41.0 million for the year ended December 31, 2023, mainly driven by the increase in the sales volume of our Bladder Cryoablation System, Pulmonary Nodule Localization Needle and Endoscopic Clip for Anastomosis.

Cost of Sales

Our cost of sales increased from RMB7.8 million for the year ended December 31, 2022 to RMB9.9 million for the year ended December 31, 2023, which was generally in line with the increase in the sales of our commercialized products in 2023.

Gross Profit and Gross Profit Margin

As a result of the foregoing, our overall gross profit increased from RMB19.4 million for the year ended December 31, 2022 to RMB31.1 million for the year ended December 31, 2023. Our overall gross profit margin increased from 71.3% for the year ended December 31, 2022 to 75.8% for the year ended December 31, 2023, primarily due to the increase in revenue from our Pulmonary Nodule Localization Needle and Endoscopic Clip for Anastomosis with higher gross profit margins.

Other Income and Gains

Our other income and gains increased from RMB11.4 million for the year ended December 31, 2022 to RMB15.0 million for the year ended December 31, 2023, mainly due to the increase in large amount of government subsidies received in 2023.

Research and Development Expenses

Our research and development expenses primarily consisted of (i) staff costs for our research and development personnel; (ii) cost of materials and consumables used; (iii) share-based payments; and (iv) clinical trial fees, including payment to hospitals, contract research organizations, site management organizations, and other service providers in connection with our research and development activities. The following table sets forth a breakdown of our research and development expenses for the years indicated:

	Year Ended December 31,			
	2023		2022	
	RMB'000	***%***	*RMB'000*	*%*
Staff cost	**43,661**	**57.4**	32,285	53.8
Cost of materials and consumables used	**13,943**	**18.3**	11,501	19.2
Share-based payments	**4,038**	**5.3**	4,612	7.7
Clinical trial fees	**9,475**	**12.4**	5,635	9.4
Depreciation and amortization	**649**	**0.9**	517	0.9
Others[(1)]	**4,363**	**5.7**	5,383	9.0
Total	**76,129**	**100**	59,933	100

Note:

(1) Primarily include intellectual property and CE certification expenses, business travel and transportation expenses incurred by our research and development staffs, animal experiment expenses and product design expenses.

Our research and development expenses increased by RMB16.2 million, or 27.0%, from RMB59.9 million for the year ended December 31, 2022 to RMB76.1 million for the year ended December 31, 2023, primarily due to (i) the increase in staff cost of RMB11.4 million as a result of the increase in the number and average salaries of our research and development personnel; and (ii) the increase in cost of materials and consumables used and clinical trial fees in ongoing research and development projects of RMB2.4 million and RMB3.8 million, respectively.

Administrative Expenses

Our administrative expenses decreased by RMB14.8 million, or 17.6%, from RMB83.8 million for the year ended December 31, 2022 to RMB69.0 million for the year ended December 31, 2023, primarily attributed to a decrease in professional service fee paid to the professional parties of Global Offering which was partially offset by an increase in staff cost.

Selling and Distribution Expenses

Our selling and distribution expenses increased by RMB1.1 million, or 24.9%, from RMB4.6 million for the year ended December 31, 2022 to RMB5.7 million for the year ended December 31, 2023, primarily due to the increase in staff cost of RMB1.0 million as a result of salary adjustment.

Other Expenses

Our other expenses remained relatively stable at RMB0.2 million for the year ended December 31, 2022 and RMB0.3 million for the year ended December 31, 2023.

Finance Costs

Our finance costs remained relatively stable at RMB0.6 million for the year ended December 31, 2022 and RMB0.7 million for the year ended December 31, 2023.

Income Tax Expenses

Our principal applicable taxes and tax rates are set forth as follows:

Chinese Mainland

Pursuant to the Corporate Income Tax Law of the PRC (the "**CIT Law**"), the Company and our PRC subsidiaries are subject to a standard corporate income tax rate of 25% on taxable income, except that Ningbo SensCure was qualified as a "High and New Technology Enterprise" to enjoy a preferential income tax rate of 15% during the Reporting Period. The related tax authorities review the "High and New Technology Enterprise" status every three years. Ningbo SensCure has been qualified and will continue to qualify as a "High and New Technology Enterprise" for three years starting from 2021.

No provision for Chinese Mainland income tax has been provided for pursuant to the CIT Law and the respective regulations, as our Group's PRC entities have no estimated assessable profits.

United States

Among our subsidiaries, Cryofocus America, Inc. was incorporated in California, the U.S. and was subject to statutory U.S. federal corporate income tax at a rate of 21% during the Reporting Period. It is also subject to the state income tax in California during the Reporting Period. No provision for federal corporate income tax and the state income tax have been provided as the subsidiary has no estimated assessable profits.

We did not record any income tax expense during the Reporting Period. Our Directors confirm that during the Reporting Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

Loss for the Year

As a result of the foregoing, our loss for the year decreased from RMB118.3 million for the year ended December 31, 2022 to RMB105.8 million for the year ended December 31, 2023.

Liquidity and Financial Resources

Our primary use of cash is to fund the development of our product candidates, clinical trials, payment for the purchase of plant and equipment, administrative expenses and other recurring expenses. Our cash and cash equivalents decreased by RMB123.0 million, or 54.3%, from RMB226.4 million as of December 31, 2022 to RMB103.4 million as of December 31, 2023. The decrease was mainly due to:

For the year ended December 31, 2023, our net cash used in operating activities was RMB95.9 million, primarily attributable to the significant research and development expenses and administrative expenses incurred by the Group during the Reporting Period. Our operating cash flow will continue to be affected by our research and development expenses.

For the year ended December 31, 2023, our net cash used in investing activities was RMB15.1 million, primarily attributable to the purchase of property, plant and equipment items of RMB15.1 million.

For the year ended December 31, 2023, our net cash used in financing activities was RMB13.7 million, primarily attributable to the payment of listing expenses during the Reporting Period.

During the Reporting Period, we mainly relied on capital contribution from Shareholders and equity financing as the main source of liquidity. Our management closely monitors the utilization of cash and cash balances and strives to maintain healthy liquidity for our business. Going forward, we believe that our liquidity requirements will be satisfied with the net proceeds from the Global Offering and cash generated from our operations.

Capital Expenditures

We regularly incur capital expenditures to expand and enhance our research and development facilities, establish our manufacturing capacities and increase our operating efficiency. Our capital expenditures primarily consisted of expenditures on machinery, office equipment, as well as leasehold improvements during the Reporting Period. The following table sets forth our capital expenditures for the years indicated:

	Year Ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Purchases of items of property, plant and equipment	**15,103**	7,010

We expect to incur capital expenditures in the next five years primarily for purchase of equipment and the construction of our manufacturing facilities.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.

Indebtedness

The following table sets forth the components of our indebtedness as of the years indicated:

	As of December 31,	
	2023	2022
	RMB'000	*RMB'000*
Lease liabilities		
Current	**3,247**	3,432
Non-current	**7,764**	7,939
Total	**11,011**	11,371

The Company incurred no borrowings during the Reporting Period. The Company had no unutilized banking facilities during the Reporting Period and up to the date of this announcement.

Key Financial Ratios

The following table sets forth the key financial ratios as at the dates indicated:

	As of December 31,	
	2023	2022
Current ratio[(1)]	**4.9**	5.8
Quick ratio[(2)]	**4.1**	5.3
Gearing ratio[(3)]	**18.5%**	17.4%

Notes:

(1) Current ratio is calculated based on total current assets divided by total current liabilities.

(2) Quick ratio is calculated based on total current assets less inventories divided by total current liabilities.

(3) Gearing ratio is calculated based on total liabilities divided by total assets and multiplied by 100%.

Capital Commitments

The Group had the following capital commitments as at the dates indicated:

	As of December 31,	
	2023	2022
	RMB'000	*RMB'000*
Contracted, but not provided for:		
Plant and machinery	**177**	2,052

Pledge of Assets

As of December 31, 2023, there was no charge on assets of the Group.

Contingent Liabilities

As of December 31, 2023, the Group did not have any material contingent liabilities, guarantees or any litigation or claims of material importance, pending or threatened against any of its member.

Significant Investments, Material Acquisitions and Disposals of Subsidiaries, Associates and Joint Ventures during the Reporting Period

The Group did not make any significant investments, material acquisitions or disposals of subsidiaries, associates and joint ventures during the Reporting Period.

Foreign Exchange Exposure

We are exposed to foreign currency risk mainly arising from cash and cash equivalents which are denominated in Renminbi, USD and HKD. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise.

Future Plans for Material Investments or Capital Assets

Save as disclosed in this announcement, the Group had not authorized any plan for any material investments or acquisitions of capital asset as of the date of this announcement.

Human Resources

As of December 31, 2023, the Group had 392 (2022: 375) full-time employees, and substantially all of them were based in China. The total employee benefits expenses of our Group, which consist of (i) terms, wages, salaries and bonuses, (ii) social security costs and (iii) equity-settled share options, for the year ended December 31, 2023 were approximately RMB116.9 million. We recruit our employees after consideration of a number of factors, including our needs and expansion plans, and the candidates' work experience and educational background. We invest in continuing training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development. In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters including terms, wages, bonuses, employee benefits, and grounds for termination. In addition, we are required under PRC law to make contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurances) and housing funds at a certain percentage of our employees' salaries, including bonus and allowances, up to a maximum amount specified by the local government.

FINAL DIVIDEND

The Board does not recommend payment of a final dividend for the Reporting Period (2022: Nil).

CORPORATE GOVERNANCE

The Directors recognize the importance of incorporating elements of good corporate governance in the management structures and internal control procedures of the Group so as to achieve effective accountability.

The Company has adopted the principles and code provisions set out in the CG Code as its own code to govern its corporate governance practices.

The Company regularly reviews its compliance with the CG Code and the Company was in compliance with all applicable code provisions set out in Part 2 of the CG Code throughout the Reporting Period.

The Company will continue to regularly review and monitor its corporate governance practices to ensure compliance with the CG Code, and maintain a high standard of corporate governance practices.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors, Supervisors and the Company's senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company's securities.

Upon specific enquiries, all Directors and Supervisors confirmed that they have complied with the Model Code throughout the Reporting Period. In addition, the Company is not aware of any non-compliance of the Model Code by the senior management of the Group throughout the Reporting Period.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY

Neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

AUDIT COMMITTEE

The Board has established the Audit Committee which consists of one non-executive Director, namely, Mr. ZHAO Chunsheng (趙春生) and two independent non-executive Directors, namely, Mr. LIANG Hsien Tse Joseph (梁顯治) and Dr. QIN Zheng (覃正). The chairperson of the Audit Committee is Mr. LIANG Hsien Tse Joseph, who holds the appropriate professional qualifications as required under Rule 3.10(2) of the Listing Rules.

The primary functions of the Audit Committee are to assist our Board in providing an independent view of our financial reporting process, internal control and risk management system, overseeing the audit process and performing other duties and responsibilities as assigned by our Board, which includes, amongst other things:

- proposing to our Board the appointment and replacement of external audit firms;
- supervising the implementation of our internal audit system;
- liaising between our internal audit department and external auditors;
- reviewing our financial information and related disclosures; and
- other duties conferred by our Board.

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and discussed matters in relation to internal control and financial reporting with the management. The Audit Committee reviewed and considered that the annual financial results for the year ended December 31, 2023 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

SCOPE OF WORK OF ERNST & YOUNG

The figures in respect of the Group's consolidated statement of financial position, consolidated statements of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2023 as set out in the preliminary announcement have been agreed by the Group's auditor, Ernst & Young, to the amounts set out in the Group's consolidated financial statements for the Reporting Period. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on this announcement.

EVENTS AFTER THE REPORTING PERIOD

Issuance of the Filing Notice by the CSRC for the H Share Full Circulation Application of the Company

On March 7, 2024, the China Securities Regulatory Commission (中國證券監督管理委員會) (the "**CSRC**") issued a filing notice to the Company (the "**Filing Notice**") in respect of an application made by the Company on behalf of certain Shareholders to the CSRC for the conversion of a total of 29,341,981 Unlisted Shares held by such Shareholders into H Shares and the listing thereof on the Stock Exchange (the "**Conversion and Listing**"). According to the Filing Notice, the filing in relation to the Conversion and Listing to the CSRC has been completed, and if the Company wishes to continue the Conversion and Listing after 12 months from the date of the issuance of the Filing Notice, an updated filing to the CSRC would be required.

As at the date of this announcement, the details of the implementation plan of the Conversion and Listing have not been finalized. The Company will make further announcement(s) on the progress of the Conversion and Listing in accordance with the requirements under the Listing Rules and/or the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

For further details, please refer to the Company's announcement dated March 11, 2024.

Proposed Amendments to the Articles of Association and Proposed Changes in Use of Proceeds from the Global Offering

On March 27, 2024, the Board announced that the Company intended to put forward a proposal to the Shareholders to amend the Articles of Association to comply with the requirements of the Listing Rules and applicable laws and regulations of the PRC, and make slight adjustments to certain provisions in the Articles of Association after taking into consideration, among others, the operation and management needs of the Company. According to the Articles of Association and the relevant laws and regulations in the PRC, the proposed amendments to the Articles of Association are subject to the approval of the Shareholders by way of a special resolution at a general meeting, H share class meeting and unlisted share class meeting of the Company. A special resolution to consider and approve the proposed amendments to the Articles of Association will be proposed at each of the AGM, H share class meeting and unlisted share class meeting of the Company.

On the same date, the Board announced that it has resolved to change the use of the unutilized portion of the net proceeds from the issue of new H Shares on the Stock Exchange in connection with the Global Offering (after deducting the underwriting fees and related listing expenses) (the "**Net Proceeds**") to deploy the unutilized Net Proceeds more efficiently and facilitate an effective use of the financial resources of the Group. According to the Articles of Association and the relevant laws and regulations in the PRC, the proposed changes in the use of the Net Proceeds are subject to the approval of the Shareholders by way of an ordinary resolution at a general meeting of the Company. An ordinary resolution to consider and approve the proposed changes in the use of the Net Proceeds will be proposed at the AGM.

A circular containing, among others, the details of the proposed amendments to the Articles of Association and the proposed changes in the use of the Net Proceeds, together with a notice of the AGM, H share class meeting and unlisted share class meeting of the Company, will be dispatched to the Shareholders in due course.

For further details, please refer to the Company's announcement dated March 27, 2024.

PRE-EMPTIVE RIGHTS

There are no provisions for pre-emptive rights under the Articles of Association, or the laws of the PRC, which would oblige the Company to offer new shares of the Company on a pro-rata basis to its existing Shareholders.

SUFFICIENCY OF PUBLIC FLOAT

According to the information that is publicly available to the Company and within the knowledge of the Board, as at the date of this announcement, the Company has maintained the public float as required under the Listing Rules.

ANNUAL GENERAL MEETING

The Company will hold the AGM on Friday, June 14, 2024. A notice of AGM will be published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.cryofocus.com), and dispatched (if necessary) to the Shareholders in the manner as required by the Listing Rules in due course.

CLOSURE OF REGISTER OF MEMBERS OF H SHARES AND ASCERTAINING OF ELIGIBILITY FOR ATTENDING THE AGM

The register of members of H Shares of the Company will be closed from Wednesday, May 15, 2024 to Friday, June 14, 2024, both days inclusive, during which no transfer of H Shares will be registered, in order to determine the holders of the H Shares who are entitled to attend and vote at the forthcoming AGM.

To be eligible to attend and vote at the AGM, all properly completed transfer documents, accompanied by relevant share certificates, must be lodged with the Company's H share registrar, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong no later than 4:30 p.m. on Tuesday, May 14, 2024 for registration.

PUBLICATION OF ANNUAL RESULTS AND 2023 ANNUAL REPORT

This annual results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.cryofocus.com). The annual report of the Company for the year ended December 31, 2023, containing all the information required by the Listing Rules, will be dispatched (if necessary) to the Shareholders and will be published on the websites of the Stock Exchange and the Company in due course.

APPRECIATION

On behalf of the Board, I would like to thank all our employees for their diligence, dedication, loyalty and integrity. I would also like to thank all our Shareholders, customers, suppliers and other business partners for their trust and support.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions shall have the following meanings.

"AGM" or "Annual General Meeting"	the forthcoming 2023 annual general meeting of the Company to be held on Friday, June 14, 2024
"Articles of Association"	the articles of association of the Company currently in force
"associate(s)"	has the meaning ascribed thereto under the Listing Rules
"Audit Committee"	the audit committee of the Board
"Board"	the board of Directors
"Board of Supervisors"	the board of Supervisors
"CE Marking" or "CE"	Conformite Europeenne, an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)
"CG Code"	the Corporate Governance Code as set out in Appendix C1 to the Listing Rules
"China" or "the PRC"	the People's Republic of China excluding, for the purposes of this announcement, Hong Kong, the Macau Special Administrative Region of the People's Republic of China and Taiwan
"Companies Ordinance"	the Companies Ordinance, Chapter 622 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
"CT"	computed tomography
"Company", "our Company" or "Cryofocus"	Cryofocus Medtech (Shanghai) Co., Ltd. (康灃生物科技(上海)股份有限公司), a joint stock company incorporated in the PRC with limited liability on July 21, 2021, or, where the context requires (as the case may be), its predecessor, Cryofocus Medtech (Shanghai) Company Limited (康灃生物科技(上海)有限公司), a limited liability company established in the PRC on March 15, 2013

"Core Product(s)"	has the meaning ascribed thereto under the Listing Rules and in this announcement, refers to the Bladder Cryoablation System (膀胱冷凍消融系統) and the Endoscopic Clip for Anastomosis (內鏡吻合夾)
"Director(s)"	the director(s) of the Company
"FDA"	the United States Food and Drug Administration
"Global Offering"	has the meaning as ascribed to it in the Prospectus
"Group", "our Group", "our", "we" or "us"	the Company and its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
"H Share(s)"	overseas listed foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are listed on the Stock Exchange
"HKD"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China
"Listing Rules"	the Rules Governing the Listing of Securities on the Stock Exchange (as amended, supplemented or otherwise modified from time to time)
"Main Board"	the stock market (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules
"Ningbo SensCure"	Ningbo SensCure Biotechnology Co., Ltd. (寧波勝杰康生物科技有限公司), a limited company established in the PRC and our wholly-owned subsidiary
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)

"NOTES"	natural orifice transluminal endoscopic surgery, a form of scarless surgery performed through cavities that connect to the outside of the body (such as the stomach wall or vagina) to access the abdominal cavity
"Prospectus"	the prospectus of the Company dated December 16, 2022
"Reporting Period"	the year ended December 31, 2023
"RMB"	Renminbi, the lawful currency of the PRC
"Share(s)"	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Unlisted Shares and H Shares
"Shareholder(s)"	holder(s) of the Share(s)
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"subsidiary(ies)"	has the meaning ascribed thereto under the Listing Rules
"Supervisor(s)"	the supervisor(s) of the Company
"United States" or "U.S."	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"Unlisted Share(s)"	ordinary share(s) issued by the Company with a nominal value of RMB1.00 each and are not listed on any stock exchange
"USD"	United States dollars, the lawful currency of the United States
"%"	per cent

By order of the Board
Cryofocus Medtech (Shanghai) Co., Ltd.
Mr. LI Kejian
Chairman of the Board

Hong Kong, March 27, 2024

As at the date of this announcement, the Board comprises Mr. LI Kejian, Mr. ZHU Jun and Mr. LIU Wei as executive Directors, Mr. LV Shiwen and Mr. ZHAO Chunsheng as non-executive Directors, and Dr. GAO Dayong, Mr. LIANG Hsien Tse Joseph, Dr. QIN Zheng and Dr. HU Henan as independent non-executive Directors.