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Sunho Biologics, Inc.

盛禾生物控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2898)

**INTERIM RESULTS ANNOUNCEMENT
FOR THE SIX MONTHS ENDED JUNE 30, 2024**

The board (the “**Board**”) of directors (the “**Directors**”) of Sunho Biologics, Inc. (the “**Company**”) is pleased to announce the unaudited consolidated interim results of the Company and its subsidiaries (collectively, the “**Group**”) for the six months ended June 30, 2024 (the “**Reporting Period**”), together with the comparative figures for the corresponding period in 2023.

HIGHLIGHTS

	Six months ended June 30,	
	2024	2023
	RMB’000	RMB’000
	(unaudited)	(unaudited)
Other income	1,782	6,024
Other Gains and Losses, Net	38,720	15
R&D Expenses	(37,708)	(24,610)
Administrative Expenses	(15,270)	(33,130)
Finance Costs	(566)	(221)
Listing Expenses	(23,035)	(9,567)
Loss for the period	(36,077)	(61,489)

The Group’s total cash and cash equivalents increased from RMB125.1 million as of December 31, 2023 to RMB493.9 million as of June 30, 2024.

**CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND
OTHER COMPREHENSIVE INCOME**

		Six months ended June 30,	
	<i>Notes</i>	2024	2023
		RMB'000	RMB'000
		(unaudited)	(unaudited)
Other income	4	1,782	6,024
Other gains and losses, net	5	38,720	15
R&D expenses		(37,708)	(24,610)
Administrative expenses		(15,270)	(33,130)
Listing expenses		(23,035)	(9,567)
Finance costs		(566)	(221)
		<hr/>	<hr/>
Loss before tax		(36,077)	(61,489)
Income tax expense	6	—	—
		<hr/>	<hr/>
Loss and total comprehensive expense for the period		(36,077)	(61,489)
		<hr/> <hr/>	<hr/> <hr/>
Loss per share			
— Basic and diluted (RMB per share)	8	(0.34)	(0.67)
		<hr/> <hr/>	<hr/> <hr/>

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>Notes</i>	As of June 30, 2024 <i>RMB'000</i> (unaudited)	As of December 31, 2023 <i>RMB'000</i> (audited)
Non-current assets			
Property and equipment		37,273	41,119
Right-of-use assets		18,055	9,587
Intangible asset		10,000	10,000
Prepayments for acquisition of equipment		4,131	103
Refundable fulfillment deposits		3,460	2,500
		72,919	63,309
Current assets			
Inventories		1,017	818
Deposits, prepayments and other receivables	9	18,658	16,256
Financial assets at fair value through profit or loss (“FVTPL”)		910	–
Other financial assets		–	49,579
Time deposits		–	35,414
Cash and cash equivalents		493,882	125,074
		514,467	227,141
Current liabilities			
Trade and other payables	10	9,568	73,960
Lease liabilities		2,211	2,178
Borrowings		22,980	–
Financial liabilities at FVTPL		–	311,525
		34,759	387,663
Net current assets/(liabilities)		479,708	(160,522)
Total assets less current liabilities		552,627	(97,213)

	<i>Notes</i>	As of June 30, 2024 RMB'000 (unaudited)	As of December 31, 2023 RMB'000 (audited)
Non-current liabilities			
Lease liabilities		<u>4,604</u>	<u>6,896</u>
		<u>4,604</u>	<u>6,896</u>
Net assets/(liabilities)		<u><u>548,023</u></u>	<u><u>(104,109)</u></u>
Capital and reserves			
Share capital		524	322
Treasury stock		(19)	(19)
Reserves		<u>547,518</u>	<u>(104,412)</u>
Total equity/(deficit)		<u><u>548,023</u></u>	<u><u>(104,109)</u></u>

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. GENERAL INFORMATION

Sunho Biologics, Inc. (the “**Company**”) was incorporated in the Cayman Islands as an exempted company registered under the Company Laws of the Cayman Islands on May 14, 2021. The shares of the Company have been listed on the Main Board of The Stock Exchange of Hong Kong Limited with effect from May 24, 2024. The Company’s ultimate controlling shareholder is Mr. Zhang Feng who achieves ultimate control through his direct or indirect interests held in the Company. The address of the registered office is PO Box 309, Uglan House, Grand Cayman, KY1-1104, Cayman Islands, and the principal place of business of the Company is 31/F, Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong.

The Company is an investment holding company. The Company and its subsidiaries (collectively referred to as the “**Group**”) are mainly committed to the develop regulate immune microenvironment by directly modulating both the innate and adaptive immune systems.

The condensed consolidated financial statements are presented in Renminbi (“**RMB**”), which is the functional currency of the Company and its subsidiaries.

2. BASIS OF PREPARATION

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting” issued by the International Accounting Standards Board (the “**IASB**”) as well as the applicable disclosure requirements of Appendix D2 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

3. PRINCIPAL ACCOUNTING POLICIES

The condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments which are measured at fair values.

Other than additional/change in accounting policies resulting from application of amendments to International Financial Reporting Standards (“**IFRSs**”), the accounting policies and methods of computation used in the condensed consolidated financial statements for the six months ended June 30, 2024 are the same as those followed in the preparation of the Group’s consolidated financial statements for each of the two years ended December 31, 2023 underlying the preparation of the historical financial information included in the accountants’ report presented in the Prospectus dated May 16, 2024.

Application of amendments to IFRSs

In the current interim period, the Group has applied the following amendments to IFRSs issued by the IASB, for the first time, which are mandatorily effective for the Group's annual period beginning on 1 January 2024 for the preparation of the Group's condensed consolidated financial statements:

Amendments to IFRS 16	Lease Liability in a Sale and Leaseback
Amendments to IAS 1	Classification of Liabilities as Current or Non-current
Amendments to IAS 1	Non-current Liabilities with Covenants
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements

The application of the amendments to IFRSs in the current interim period has had no material impact on the Group's financial positions and performance for the current and prior periods and/or on the disclosures set out in these condensed consolidated financial statements.

4. OTHER INCOME

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Government grants	38	6,000
Interest income from financial institutions	1,744	24
	<u>1,782</u>	<u>6,024</u>

5. OTHER GAINS AND LOSSES, NET

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Realized gain on other financial assets	1,022	–
Gain from fair value change of financial liabilities at FVTPL	34,782	–
Net foreign exchange gains	2,880	12
Others	36	3
	<u>38,720</u>	<u>15</u>

6. INCOME TAX EXPENSE

No income tax expense has been incurred by the Group during the six months ended June 30, 2024 and 2023 as there was no assessable profits derived from or earned for any of the periods presented.

7. DIVIDENDS

No dividends were paid, declared or proposed during the interim period. The directors of the Company have determined that no dividend will be paid in respect of the interim period (six months ended June 30, 2023: nil).

8. LOSS PER SHARE

The calculation of the basic and diluted loss per share attributable to the owners of the Company is based on the following data:

	Six months ended June 30,	
	2024	2023
	(unaudited)	(unaudited)
Loss (RMB'000)		
Loss for the period attributable to the owners of the Company for the purpose of calculating basic and diluted loss per share	<u>(36,077)</u>	<u>(61,489)</u>
Number of shares ('000)		
Weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share	<u>105,520</u>	<u>91,746</u>

9. DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	As of June 30, 2024	As of December 31, 2023
	RMB'000	RMB'000
	(unaudited)	(audited)
Analyzed as:		
Non-current	3,460	2,500
Current	<u>18,658</u>	<u>16,256</u>
	<u>22,118</u>	<u>18,756</u>

10. TRADE AND OTHER PAYABLES

The average credit period on purchases of materials and services of the Group is 10–60 days.

The following is an aging analysis of payables for payables for R&D costs, presented based on the invoice dates at the end of each reporting period:

	As of June 30, 2024 RMB'000 (unaudited)	As of December 31, 2023 RMB'000 (audited)
0–90 days	–	140
Over 90 days	<u>1,165</u>	<u>1,165</u>
	<u><u>1,165</u></u>	<u><u>1,305</u></u>

MANAGEMENT DISCUSSION AND ANALYSIS

BUSINESS REVIEW

Founded in 2018, we are a clinical stage biopharmaceutical company that focuses on the discovery, development and commercialization of biologics for the treatment of cancers and autoimmune diseases. We have three Core Products, namely, IAH0968, IAP0971 and IAE0972, all of which are developed in-house. IAH0968 is an antibody-dependent cell-mediated cytotoxicity (“**ADCC**”) enhanced monoclonal antibody (“**mAb**”), and we have initiated Phase II clinical trials for biliary tract carcinoma (“**BTC**”) and colorectal cancer (“**CRC**”). IAP0971 and IAE0972 are both immunocytokines and we have completed Phase I clinical trials for advanced solid tumors including non-small cell lung cancer (“**NSCLC**”) and CRC.

R&D of product candidates

Our R&D capabilities cover development of candidates in the forms of mAbs, bispecific antibodies (“**bsAbs**”), and fusion proteins, some of which extend indications into treatment areas beyond oncology. Our Core Product IAH0968 is an ADCC enhanced mAb targeting human epidermal growth factor receptor 2 (“**HER2**”) with 100% fucose knock out, which greatly enhances the binding affinity of its fragment crystallizable (“**Fc**”) to its receptor FcγRIIIa. ADCC is an immune mechanism through which Fc receptor-bearing effector cells including natural killer (“**NK**”) cells and CD+8 T cells can recognize and kill antibody-coated target cells expressing tumor- or pathogen-derived antigens on their surface. It is one of the most important methods for antibody drugs to kill tumor cells. The typical ADCC involves activation of NK cells by antibodies in a multi-tiered progression of immune control. A NK cell expresses Fcγ receptors (“**FcγR**”). These receptors recognize and bind to the Fc domain of an antibody, and the antigen binding fragment (“**Fab**”) domain of which binds to the tumor associated antigen (“**TAA**”) on the tumor cell. When both TAA and FcγR are engaged respectively by the Fab and Fc portions of the antibody, ADCC is initiated, since this creates a bridge from the tumor cell to the effector cell. However, the natural affinity between antibodies and FcγR is relatively weak, and Fc engineering to enhance affinity has become a common method.

Our featured products, immunocytokines, are designed through our proprietary and internally developed Armed ImmunoCytokine Platform (“**AIC™ Platform**”) by our core R&D team in researching antibody-cytokine fusion proteins. They function through diverse mechanisms of action yet share a similar structure comprising an antibody or quasi-antibody moiety that targets tumors and blocks signaling pathways regulating tumor growth and proliferation, and cytokine payloads that activate the immune system within the tumor microenvironment (“**TME**”). Such a design is expected to overcome drawbacks of conventional cytokine-based drugs, such as short half-lives, systemic cytotoxicity and modest efficacies due to cytokine pleiotropy and off-target effects. It is expected to achieve enhanced antitumor effects through the synergy between the antibody and cytokine payloads, which potentially address the needs of cancer patients who suffer from disease progression related to the immunosuppressive TME and drug resistance.

IAH0968

Our Core Product IAH0968 is an internally developed, the first anti-HER2 antibody in clinical stage with 100% fucose-removal. Antibodies consist of two structural regions, Fab and Fc. Unlike Fab region, which defines the specific target of an antibody, Fc region mediates ADCC by activating the immune system through engaging various Fc receptors. Studies of the structure of the Fc region of antibodies and its receptor FcγRIIIa complex revealed that the core fucose of the Fc region is accommodated at a place that interferes with the binding between the Fc region and FcγRIIIa, and thus reducing the affinity between them and resulting in lower ADCC activity. Therefore, modifying to remove fucose is desirable to better recruit immune cells, resulting in enhanced ADCC activity. As a result, this approach has been widely attempted in the biopharmaceutical industry. However, despite numerous attempts by multiple players to modify antibodies through various approaches, such as Fc point specific mutation and fucose removal, most resulting antibodies still contain a certain percentage of core fucose.

The Phase I clinical trial showed that IAH0968 was well tolerated and exhibited antitumor activities in patients with advanced HER2+ malignant solid tumors including breast cancers, gastric cancers, CRC and BTC with drug resistance to trastuzumab, pertuzumab, cetuximab, docetaxel, oxaliplatin, capecitabine, irinotecan, nab-paclitaxel and apatinib, or anti-PD-1 mAbs. Data showed that only one DLT was found at dosage 10mg/kg, and no MTD was reached. While no head-to-head study was conducted, the Phase I clinical data showed that IAH0968 achieved significantly improved objective response rate (“**ORR**”) and disease control rate (“**DCR**”) in heavily pretreated metastatic CRC and BTC patients, when compared to the historical data of current treatments. For heavily pretreated metastatic CRC and BTC patients, the ORR was 40%, and DCR was 80%.

We obtained the IND approval for conducting Phase I and Phase II clinical trials of IAH0968 from the National Medical Products Administration (“NMPA”) in October 2020, commenced the Phase I clinical trial in August 2021, and completed the Phase I clinical trial of using IAH0968 as a monotherapy for heavily pretreated patients with advanced HER2+ malignant solid tumors in March 2023. Based on the encouraging clinical data from the Phase I trial, we obtained IND approvals from the NMPA to conduct Phase II and Phase III clinical trials of using IAH0968 in combination with chemotherapy for first-line treatment of inoperable HER2+ advanced or metastatic CRC, and to conduct Phase II clinical trials of using IAH0968 in combination with chemotherapy for first-line treatment of HER2+ metastatic BTC patients in September 2022. We have dosed the first CRC patient of the Phase IIa trial in May 2023, and also have dosed the first BTC patient of the Phase II clinical trial in August 2023. We entered a Phase IIb/III clinical trial for CRC in January 2024, and expect to complete the Phase IIb trial for CRC in the fourth quarter of 2024. We also expect to complete the Phase II clinical trial for BTC in the third quarter of 2025.

IAP0971

Our Core Product IAP0971 is an internally developed, dual-moiety, anti-programmed death-1 (“**PD-1**”) antibody-IL-15/IL-15R α heterodimer dual T cell and NK cell agonist. IAP0971 is expected to synergistically strengthen the antitumor activity through blockade of the PD-1/its ligand (“**PD-L1**”) signaling pathway and accumulating IL-15 at the targeted tumor site to activate its nearby immune cells, including CD8+ T cells and NK cells, directly activating both innate and adaptive immune systems.

In July 2023, we completed Phase I clinical trial of IAP0971 for advanced malignant tumors. Phase I clinical data showed that IAP0971 exhibited a favorable safety profile at up to 200 μ g/kg in patients with advanced malignant tumors, with no dose-limiting toxicity (“**DLT**”) and maximum tolerable dose (“**MTD**”) observed. Preliminary antitumor efficacy was observed in four patients treated with IAP0971 as later-line therapy. These four patients include one with CRC, one with cervical cancer, and two with NSCLC, and those patients underwent multiple rounds of treatments including chemotherapy, targeted therapy, immunotherapy and/or their combination, and experienced disease progress and metastases. After receiving IAP0971 for two treatment cycles, all four patients achieved stable disease (“**SD**”). Especially, one NSCLC patient complicated with adrenal gland and other metastases was resistant to several prior treatments, including chemotherapy regimes such as multiple paclitaxel-containing combination, and combination therapies with targeted therapy and immunotherapy, such as erlotinib, camrelizumab, sintilizumab and bevacizumab. This patient received 120 μ g/kg IAP0971 for two treatment cycles and achieved SD. The other NSCLC patient complicated with pleura or pleural effusion metastases was resistant to several prior treatments, and also achieved SD after two cycles of 200 μ g/kg IAP0971 administration.

In January 2022 and December 2021, we obtained IND approvals from both the NMPA and the FDA for conducting Phase I and Phase II clinical trials in patients with advanced malignant tumors, respectively. We commenced the Phase I clinical trial in China in June 2022 according to a protocol approved by both the NMPA and the FDA, and completed the Phase I clinical trial in July 2023. Based on an interview conducted with a senior examiner of the NMPA with the attendance of professional parties, the NMPA had no objection for us to commence a planned Phase II clinical trial of IAP0971 as a monotherapy for locally advanced unresectable or metastatic NSCLC. We plan to initiate a Phase II clinical trial for IAP0971 in China in the third quarter of 2024.

IAE0972

Our Core Product IAE0972 is an internally developed, dual-moiety, anti-epidermal growth factor receptor (“**EGFR**”) antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. Like IAP0971, IAE0972 is also expected to achieve synergistical antitumor activities leveraging the advantages of immunocytokine yet through a different combination of antibody target and cytokine payload. It is designed to blockade the EGFR signaling pathway and specifically deliver IL-10 to the targeted tumor site to activate CD8+ T cells, and potentially NK cells.

In our Phase I clinical trial of IAE0972 for advanced solid tumors, we recruited 14 patients with advanced esophageal squamous cell carcinoma, rectal cancer, gastric cancer, pancreatic cancer, small cell lung cancer (“**SCLC**”) or NSCLC who progressed from at least one line of treatment. We completed dose escalation for 1 µg/kg, 10 µg/kg, 100 µg/kg, 0.3mg/kg, 1.0mg/kg and 2.5mg/kg of IAE0972, and only observed one Grade 3 adverse events. No DLT occurred and MTD was not reached. Preliminary efficacy was observed in multiple heavily pretreated patients who failed all previous therapies. A CRC patient complicated by lung metastasis, who has received multiple lines of prior treatments including standard mFOLFOX6 (5-fluorouracil, leucovorin and oxaliplatin) and CapeOX (capecitabine and oxaliplatin) regimens, achieved SD after given 10µg/kg of IAE0972 for two treatment cycles. Another patient with rectal cancer and lung metastasis and lymph node metastasis, who had experienced recurrence after received two resections, achieved SD after receiving 1.0mg/kg of IAE0972 monotherapy for two cycles.

Other pipeline products

In addition to our product candidates mentioned above, we are developing a number of clinical stage and IND-enabling product candidates that we believe have high commercial viability. As of June 30, 2024, except for IBC0966, we maintained the global rights to develop and commercialize them. For IBC0966, we have exclusive rights to develop, manufacture and commercialize in Greater China including mainland China, Hong Kong, Macau and Taiwan and have partial overseas rights.

- **IBB0979:** IBB0979, another immunocytokine developed by us, is a clinical stage, dual-moiety, anti-B7H3 antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells to fight against tumors. We obtained the approval for conducting Phase I and Phase II clinical trials in patients with locally-advanced or metastatic solid tumors from the FDA and the NMPA in October 2022 and November 2022, respectively. The Phase I clinical trial is currently on-going, with the first patient dosed in July 2023. We expect to complete the Phase I clinical trial in the fourth quarter of 2024. Since B7H3 is overexpressed in a wide range of cancers including glioma, thyroid, lung, head and neck, rectal, prostate, breast, skin, renal cell, and ovarian cancers, it has the potential to become a next-generation therapy for resolving T cell exhaustion in cancer patients.
- **IBC0966:** IBC0966 is a clinical stage anti-PD-L1 antibody-SIRP α bifunctional fusion protein that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects and induce long-lasting tumor-specific immune responses. It is designed to bind to PD-L1 and trigger blockage of the PD-1/PD-L1 signaling pathway to enable T cells to recognize and kill targeted cancer cells, and in the meantime deliver SIRP α to the targeted TME to interact with CD47 to block the “don’t eat me” signal of macrophages for tumor cell killing. In March 2021, we obtained the IND approval from the NMPA for conducting clinical trials of IBC0966. We completed the Phase I clinical trial of IBC0966 as monotherapy for advanced malignant tumors in December 2023, and expect to enter a Phase II clinical trial in the second quarter of 2025. We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. (“**ImmuneOnco**”) to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau and Taiwan.

- **IBD0333:** IBD0333 is a clinical stage 4-1BB and CD24 bsAb that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects with reduced hepatotoxicity. It is designed to bind to 4-1BB, a robust immune cell activator expressed by CD8+ T cells as well as DC cells, monocytes, B cells, mast cells, NK cells and neutrophils, and CD24, a promising target that plays a key role in tumor evasion in CD24-sialic-acid-binding Ig-like lectin 10 (“**Siglec-10**”) axis and thus is highly expressed in many cancer types. We have obtained IND approvals from the FDA in June 2023 and from the NMPA in July 2023. We initiated a Phase I clinical study in March 2024 in patients with locally advanced/metastatic solid tumors, and expect to complete the Phase I study in the third quarter of 2025.
- **IAN0982:** IAN0982 is an internally developed multi-specific innate effector activator based on our AIM™ Platform. We are developing IAN0982 as a monotherapy or in combination with other therapeutics including chemotherapy and immunotherapy for the treatment of advanced solid tumors. Our IND application for IAN0982 is expected to be submitted to the NMPA and the FDA in the second quarter of 2025.
- **ISH0988:** ISH0988 is an internally developed anti-inflammatory and tissue protective bifunctional fusion protein based on our AIM™ Platform. We are developing ISH0988 as a monotherapy for the treatment of inflammatory bowel disease. Our IND application for ISH0988 is expected to be submitted to the NMPA and the FDA in the second quarter of 2025.
- **ISH0613:** ISH0613 is an internally developed bifunctional antibody fusion protein that simultaneously inhibits B cell activation and IFN α secretion based on our AIM™ Platform. We are developing ISH0613 as a monotherapy for the treatment of systemic lupus erythematosus (“**SLE**”). Our IND application for ISH0613 is expected to be submitted to the NMPA and the FDA in the fourth quarter of 2024.

The following diagram summarizes the status of the product pipeline of the Group as of June 30, 2024:



★ Core Product █ NMPA █ FDA █ Preclinical stage

Abbreviations: 1L = first-line; 2L = second-line; 3L = third-line; ADCC = antibody-dependent cell-mediated cytotoxicity; AEA™ = ADCC Enhanced Antibody Platform; AIC™ = Armed ImmunoCytokine Platform; AIM™ = Armed Innate Effector Multispecific Platform; BCG = Bacillus Calmette-Guerin; bsAb = bispecific antibody; bsFp = bispecific fusion protein; CapeOX= capecitabine and oxaliplatin; Chemo = chemotherapy; FDA = U.S. Food and Drug Administration; GC = gemcitabine and cisplatin; IND = Investigational New Drug; mAb = monoclonal antibody; Mono = monotherapy; NMPA = National Medical Products Administration; NSCLC = non-small cell lung cancer; NMIBC = non-muscle invasive bladder cancer; BTC = biliary tract carcinoma; CRC = colorectal cancer; HBV = hepatitis B virus; HNSCC = head and neck squamous cell carcinoma; HCC = hepatocellular carcinoma; IBD = inflammatory bowel disease; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter; 1H = first half; SLE = systemic lupus erythematosus.

Notes:

- * All the product candidates are administered intravenously, except for IAP0971 for the treatment of 2L/3L NMIBC, which will be administered through intravesical instillation, as well as IAP0971 for the treatment of NSCLC, which will be administered through subcutaneous injection.
- ** We acquired exclusive rights from ImmuneOnco to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau and Taiwan, as well as 7.5% of interests in the overseas rights of IBC0966. For more information, see “Business — Collaboration Arrangement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966” in the Prospectus.
- *** We have completed Phase I clinical trials of relevant products as monotherapy, and plan to leverage data collected in the respective trials and directly seek IND approvals from competent regulatory authorities to conduct Phase II clinical trials of relevant products as combination therapy.

For further details of the product candidates of the Group, please refer to the Prospectus.

Warning: There is no assurance that we will ultimately be able to develop and market our Core Products or any of our pipeline products successfully.

OUR PLATFORMS

Our commitment to innovation is evident and supported by our proprietary technology platforms, which include (i) AIC™ Platform, a scalable platform mainly concentrated on antibody-cytokine fusion protein development, (ii) ADCC Enhanced Antibody Platform (“**AEA™ Platform**”), a FUT8 knock-out cell line constructed to enhance the cytotoxicity of antibodies, and (iii) Armed Innate Effector Multi-specific Platform (“**AIM™ Platform**”), a platform that focuses on the development of innate immunity stimulator-based bispecific/multi-specific antibodies. Each of them is designed for addressing technical difficulties and drug resistance faced in developing immunotherapies and achieving optimized treatment effects. Since their launch, we have developed IAP0971, IAE0972, IBB0979, ISH0988 and ISH0613 based on AIC™ Platform, IAH0968 based on AEA™ Platform, and IAN0982 based on AIM™ Platform.

AIC™ Platform

Our AIC™ Platform is prominently positioned in the field of immunocytokine development from multiple aspects, including cytokine selection and optimization, antibody selection and engineering, structural design and engineering, and production through customized cell line. It is a comprehensive research engine that includes not only a pool of intact immunoglobulin G (“**IgG**”) antibodies and cytokines, but also functional antibody fragments and other types of immune system modulators. It is able to generate products ranging from immunocytokines to other bifunctional fusion proteins. Our clinical stage drug candidates IAP0971, IAE0972 and IBB0979, and preclinical stage drug candidates ISH0988 and ISH0613 were developed based on the AIC™ Platform.

Core competencies of our AIC™ Platform include mechanism of action (“**MoA**”)-based antibody-cytokine selection, biology-oriented structural design and protein engineering, and production through customized cell lines.

- MoA-based antibody-cytokine selection is the cornerstone to achieve desired synergistic effects between antibody and cytokine. For example, selection of anti-PD-1 antibody and IL-15 cytokine for developing IAP0971 is grounded on their shared action site on the same T/NK cells, leading to great cis-synergy. The combination of anti-EGFR antibody and IL-10 is selected based on the potential engager effects it can produce. Specifically, IAE0972 can engage CD8+ T cells through IL-10 while simultaneously targeting tumor cells through the EGFR antibody moiety.

- Structural design and protein engineering module enable us to structurally design and modify our products to achieve improved safety and efficacy profile while reducing manufacturing cost and enhancing product quality manageability. Structural modifications that we are capable to perform through our AIC™ Platform include antibody and cytokine engineering, deglycosylation, linker/spacer design and optimization, and tertiary structure alteration.
- Production through customized cell lines is another important function performed by our AIC™ Platform. The cell lines we constructed for producing immunocytokines and other bifunctional fusion proteins are obtained after undergoing multiple rounds of metabolic and growth optimization and are of high expression capacity and excellent purification yield. Coupled with unique cytokine-specific codon optimization, stably expressed vehicles with optimized expression cassettes and our high-throughput screening system, it is able to reach an expression level of 4g/L and one-step affinity chromatography purity of 86%.

AEA™ Platform

Our AEA™ Platform is a biologically engineered Chinese hamster ovary (“CHO”) cell line with the FUT8 knocked-out to generate antibodies with enhanced ADCC and improved antitumor activities. Through this bioengineering modification, the CHO cell line will not be able to catalyze the transfer of fucose residue from its donor to its target, and thus is not able to produce any antibody that carries fucose. Because absence of core fucose on the Fc region has been shown to increase the Fc region’s binding affinity (up to 100 times) to its receptor FcγRIIIa present on immune effector cells, fucose-negative antibodies are expected to have enhanced ADCC activities through better activating immune effector cells.

Comparing to other platforms that aim to achieve enhanced ADCC by removing fucose from antibodies, AEA™ Platform is expected to produce antibodies with 0% of fucose, which stably and thoroughly enhances the ADCC of antibodies and simplifies quality control of the products.

AIM™ Platform

Our AIM™ Platform focuses on designing multi-functional biological products by engaging the innate immune system for cancer immunotherapy. It selects tumor associated antigen antibodies for cancer targeting, receptors agonist antibodies for innate effector activation, and cytokines and other TME factors for immune modulation to design multispecific antibody fusion proteins, and evaluates them in terms of expression, target binding, in vitro and in vivo biological activities, as well as druggability. Currently, we have developed several categories of our proprietary AIM™ Platform that allow us to explore the combination of innate immunity stimulators with different types and numbers of targets, which provide us with abundant flexibility and diversity of various types of TME modulations for different clinical indications.

R&D

We consistently devote resources to R&D to pave for long-term growth. We believe the diversification and expansion of our product pipeline through both in-house R&D and through external collaboration are critical to our long-term competitiveness and success. Our fully-integrated biological therapeutic platform encompasses all the key biologic drug development functionalities, enabling us to identify and address potential clinical and manufacturing needs early in the development process, so we can direct our efforts towards biologics with best potential. Our platform spans from the early phase of identifying demand, developing core technologies, managing clinical trials, to the manufacturing of products. We believe that our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through changing market needs, enable us to improve pipeline viability and expedite product development cycle at lower cost.

COLLABORATION ARRANGEMENT

In October 2019, we entered into a collaboration agreement (the “**IBC0966 Agreement**”) with ImmuneOnco with respect to the technology transfer, development, manufacture and commercialization of IBC0966. Pursuant to the IBC0966 Agreement, ImmuneOnco transferred to us (i) all of its rights and interests, including but not limited to development, production, regulatory filings and commercialization, in relation to IBC0966 in mainland China, Hong Kong, Macau and Taiwan (the “**Territory**”); (ii) all related patents, if applicable, registered in the Territory; and (iii) all technical data and analytical methods relating to the development of IBC0966. Accordingly, ImmuneOnco has transferred to us its invention patent in mainland China in relation to IBC0966 (patent number: CN111278865B), which covered all the key characteristics of IBC0966, and we have completed the administrative registration of the transfer. The application of this patent was filed on October 24, 2018 and the patent will expire on October 24, 2038.

Manufacturing

We have established our own global GMP-compliant manufacturing facilities, which meet both clinical and commercial production demands to quantity, quality and dosage form of our product candidates. We currently have four active drug substance production lines up to a total capacity of 1,600L, including three 200L and one 1,000L disposable bioreactors. We have successfully completed over 30 production batches of immunocytokines, mAbs, bsAbs and fusion proteins, which fulfilled the needs for performing preclinical studies, pilot production of antibody drugs and conducting early phase clinical trials. We have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in November 2023. When putting into operation, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house. Our drug product facility includes one commercial-scale liquid injection filling production line and one commercial scale lyophilized powder production line, which enables us to prepare biological products into various dosage forms according to different needs.

FUTURE AND OUTLOOK

We plan to implement the following strategies to achieve our goals and visions:

- Focus on the development of immunocytokines to enhance position in this drug development field;
- Continue advancing selected pipeline products with great clinical value and commercial potential;
- Expand our GMP-compliant manufacturing facility to enhance our production capabilities and start to assemble our commercial team;
- Actively seek international collaboration opportunities to maximize value of our assets and increase brand awareness on a global scale; and
- Continue to focus on selecting and retaining top talents to fuel our innovation.

FINANCIAL REVIEW

The following discussion is based on and should be read in conjunction with the financial information and accompanying notes included elsewhere in this announcement.

Other Income

During the Reporting Period and the six months ended June 30, 2023, other income consisted of (i) government grants by the PRC local government authorities mainly to support our R&D activities; and (ii) interest income from financial institutions. The following table sets forth a breakdown of our other income for the Reporting Period and the six months ended June 30, 2023:

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	38	6,000
Interest income from financial institutions	1,744	24
Total	1,782	6,024

Other income of the Group decreased by approximately 70.4% from approximately RMB6.0 million for the six months ended June 30, 2023 to approximately RMB1.8 million for the Reporting Period, which was primarily due to the decrease in government grants in the Reporting Period.

Other Gains and Losses, Net

During the Reporting Period and the six months ended June 30, 2023, our net other gains and losses amounted to approximately RMB38.7 million and approximately RMB0.02 million, consisting of (i) realized gains on other financial assets measured at FVTPL, mainly representing gains on the wealth management products we purchased; (ii) gain from fair value change of financial liabilities at FVTPL, mainly representing fair value gains of the preferred shares issued to the pre-IPO investors of our Company's global offering; and (iii) net foreign exchanges losses or gains.

R&D Expenses

During the Reporting Period and the six months ended June 30, 2023, our R&D expenses consisted of (i) contract research expenses in relation to the engagement of contract service providers; (ii) staff costs incurred by our R&D personnel; (iii) depreciation and amortization expenses in relation to our R&D machinery and equipment; (iv) material consumed in the course of our R&D activities; (v) application fees for our patents and IND applications; (vi) share-based compensation; and (vii) other R&D expenses, mainly comprising traveling and transportation expenses of our R&D personnel, utilities incurred for our R&D activities and other miscellaneous expenses.

The following table sets forth a breakdown of our R&D expenses for the periods indicated.

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Contract research expenses	4,559	8,569
Staff costs	7,614	7,556
Depreciation and amortization expenses	3,845	3,864
Materials consumed	1,447	2,174
Application fees	465	660
Share-based compensation	18,189	453
Others	1,589	1,334
Total	37,708	24,610

The R&D expenses for the Reporting Period increased from approximately RMB24.6 million in the first half of 2023 to approximately RMB37.7 million in the Reporting Period, which was mainly due to the increase in share-based compensation of our R&D personnel.

Administrative Expenses

During the Reporting Period and the six months ended June 30, 2023, our administrative expenses amounted to approximately RMB15.3 million and approximately RMB33.1 million, consisting of (i) general office expenses mainly comprising office product expenses, conference expenses and traveling and transportation expenses of administrative personnel; (ii) employee benefits expenses mainly relating to salaries, bonus and other welfare for our administrative employees; (iii) depreciation and amortization expenses for assets which were used for administrative purpose; (iv) professional service fees, which were primarily for related consulting, auditing and asset valuation in relation to corporate administration and restructuring; (v) share-based compensation; and (vi) other administrative expenses mainly including tax and surcharges and other miscellaneous expenses. The decrease in administrative expenses for the Reporting Period as compared to the six months ended June 30, 2023 was primarily due to a decrease in share-based compensation as we recorded share-based compensation during the six months ended June 30, 2023 in relation to the RSUs transferred to Mr. Zhang Feng, while there was no such circumstance occurred during the Reporting Period.

Finance Costs

During the Reporting Period and the six months ended June 30, 2023, our finance costs amounted to approximately RMB0.6 million and approximately RMB0.2 million, consisting of (i) interest expenses on our borrowing from a related party; (ii) interest expenses on bank borrowings; and (iii) interest expenses on our lease liabilities. The increase in finance costs for the Reporting Period as compared to the six months ended June 30, 2023 was primarily due to the increase in interest expenses on bank borrowings and the increase in interest expenses on lease liabilities.

Listing Expenses

Listing expenses represent expenses incurred for our listing and global offering. During the Reporting Period and the six months ended June 30, 2023, we recorded listing expenses of approximately RMB23.0 million and approximately RMB9.6 million, respectively.

Income Tax Expenses

Our income tax expense for the Reporting Period was nil (six months ended June 30, 2023: nil).

Loss for the Period

As a result of the foregoing, our loss for the period decreased from approximately RMB61.5 million for the six months ended June 30, 2023 to approximately RMB36.0 million for the Reporting Period.

Liquidity and Financial Resources

We have continued to maintain a healthy and sound financial position and have followed a set of funding and treasury policies to manage our capital resources and mitigate potential risks involved. As of June 30, 2024, the Group's total cash and cash equivalents amounted to approximately RMB493.9 million, representing an increase of approximately 294.9% as compared to approximately RMB125.1 million as of December 31, 2023. Such increase was primarily due to the receiving of proceeds from our Company's global offering and the maturity of financial products and time deposits.

As of June 30, 2024, the Group did not have any time deposits.

As of June 30, 2024, current assets of the Group amounted to approximately RMB514.5 million; and current liabilities of the Group amounted to approximately RMB34.8 million, including interest-bearing bank borrowings of approximately RMB23.0 million. Bank borrowings of our Group were denominated in RMB, and were unsecured and unguaranteed, payable within 12 months and carried an annual interest rate ranging from 3.45% to 3.80%.

Indebtedness

The following table sets forth the breakdown of our lease liabilities, interest-bearing bank borrowings and convertible redeemable preferred shares as of the dates indicated:

	As of June 30, 2024 RMB'000	As of December 31, 2023 RMB'000
Secured and unguaranteed		
Lease liabilities	43	42
Unsecured and unguaranteed		
Lease liabilities	6,772	9,032
Financial liabilities at FVTPL	–	311,525
Amounts due to a related party	–	60,285
Bank borrowings	22,980	–
Total	29,795	380,884

Save as discussed above, we did not have any other material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptance (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of June 30, 2024.

Gearing Ratio

As of June 30, 2024, the gearing ratio, calculated by dividing total liabilities by total assets and multiplied by 100%, decreased to approximately 6.7%, as compared with approximately 135.8% as of December 31, 2023.

Significant Investments, Material Acquisitions and Disposal

On June 28, 2024, Sunho (HK) Limited (as the subscriber), entered into the subscription letters, pursuant to which Sunho (HK) Limited has agreed to subscribe for three funds. Please also refer to the announcement of the Company dated June 28, 2024 and the supplemental announcements of the Company dated July 5, 2024 and July 9, 2024. Save as disclosed above, the Group did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the six months ended June 30, 2024.

Capital Commitments

As of June 30, 2024, we had capital commitment of RMB25.5 million, primarily arose from the contracts we entered into with suppliers for the acquisition of equipment and the contract we entered into to acquire the land use right to support the construction of our production lines and the expansion of our business operations (as of December 31, 2023: RMB18.6 million).

Contingent Liabilities

Except for the under provision of social insurance and housing provident fund contributions, we did not have any material contingent liabilities as of December 31, 2023 and June 30, 2024. For the related risk, see “Risk Factors — Risks Relating to Our Operations — Any failure to comply with the PRC regulations regarding contribution of social insurance premium or housing provident funds may subject us to fines and other legal or administrative measures” in the Prospectus.

Pledge of Assets

As of June 30, 2024, the Group has not pledged or charged any assets (as of December 31, 2023: nil).

Foreign Exchange Exposure

Foreign currency risk refers to the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which our Group conducts business may affect our financial condition and results of operation. The Group mainly operates in the PRC and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to HK\$ and USD. The conversion of foreign currencies into RMB, including HK\$ and the USD, has been based on rates set by the People’s Bank of China. The Group primarily limits our exposure to foreign currency risk by closely monitoring the foreign exchange market. During the Reporting Period, the Group did not enter into any currency hedging transactions.

Use of Proceeds

The Group received net proceeds (after deduction of underwriting commissions and related costs and expenses) from our Company's global offering of approximately HK\$391.6 million. The net proceeds from our Company's global offering have been and will be used in accordance with the purposes as set out in the Prospectus. The following table sets forth the use of the net proceeds from our Company's global offering as of June 30, 2024:

Proposed use of proceeds	Allocation of net proceeds from the global offering (HK\$ million)	Percentage of total net proceeds (%)	Utilized amount (as of June 30, 2024) (HK\$ million)	Unutilized amount (as of June 30, 2024) (HK\$ million)
For ongoing and planned clinical trials of IAH0968 in China	110.4	28.2	–	110.4
For ongoing and planned clinical trials of IAP0971 in China	140.1	35.8	–	140.1
For ongoing and planned clinical trials of IAE0972 in China	141.1	36.0	–	141.1
Total	391.6	100	–	391.6

The Company expects that the net proceeds from the global offering will be used up by 2026.

Events after the Reporting Period

There has been no important event subsequent to the Reporting Period and up to the date of this announcement, which would affect the Group's business operations in material aspects.

Employee and Remuneration

As of June 30, 2024, our Group had a total of 124 employees. The total remuneration cost of our Group for the Reporting Period was RMB28.5 million, as compared to RMB37.6 million for the six months ended June 30, 2023. We have designed an evaluation system to assess the performance of its employees periodically. Such system forms the basis of our determinations of whether an employee should receive a salary raise, bonus, or promotion. We believe the salaries and bonuses that the employees receive are competitive with market rates.

We place strong emphasis on providing training to our employees in order to enhance their technical and product knowledge. We design and offer different training programmes for our employees in various positions.

We make contributions to the social insurance and housing provident fund for all of our employees in the PRC. We have adopted the RSU Scheme to recognize and motivate the contributions by the relevant participants and give incentives thereto in order to retain them, as well as to attract suitable personnel for further development of our Group. Please refer to “D. RSU Scheme” in Appendix IV to the Prospectus for a summary of the principal terms of the RSU Scheme.

OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company has adopted the principles and code provisions in the Corporate Governance Code (“**CG Code**”) set out in Appendix C1 to the Listing Rules and has complied with all applicable code provisions of the CG Code from the Listing Date to June 30, 2024.

Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors. Having made specific enquiries with all Directors, each of them has confirmed that he/she has complied with the Model Code from the Listing Date to June 30, 2024. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities from the Listing Date to June 30, 2024 (including sale of treasury share, if any).

Audit Committee

The Company has established the Audit Committee with written terms of reference in compliance with the CG Code. As of the date of this announcement, the Audit Committee consists of three independent non-executive Directors, namely Mr. CHAN Heung Wing Anthony, Ms. FENG Lan and Mr. SHI Luwen. Mr. CHAN Heung Wing Anthony is the chairman of the Audit Committee, who possesses suitable professional qualifications.

Review of Interim Results

The Audit Committee has reviewed the interim results for the Reporting Period (with no disagreement), together with the management of the Company. The Audit Committee has also reviewed the accounting principles and practices adopted by the Group and discussed, risk management, internal control and financial reporting matters of the Group for the Reporting Period.

Interim Dividend

The Board does not recommend the payment of an interim dividend for the Reporting Period (for the six months ended June 30, 2023: nil).

Publication of Interim Results Announcement and Interim Report

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.sunho-bio.com.cn).

The interim report of the Company for the six months ended June 30, 2024 containing all the information required by the Listing Rules will be sent to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

DEFINITIONS

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

“Audit Committee”	the audit committee of the Board
“Board”	the board of Directors
“Company” or “we”	Sunho Biologics, Inc. (盛禾生物控股有限公司), an exempted company with limited liability incorporated in the Cayman Islands on May 14, 2021 and the issued Shares of which are listed on the Stock Exchange (Stock Code: 2898)
“Core Products”	namely, IAH0968, IAP0971 and IAE0972
“Director(s)”	the director(s) of our Company
“FDA”	U.S. Food and Drug Administration
“Group”	collectively, the Company and its subsidiaries
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic of China
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application, or CTA, in China
“Listing Date”	May 24, 2024
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Model Code”	Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules

“Nanjing Bode”	Nanjing Bode Biological Pharmaceutical Co., Ltd.* (南京博德生物製藥有限公司), a company established in the PRC with limited liability
“PRC” or “China” or “Mainland China”	the People’s Republic of China, which for the purpose of this announcement, excludes Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“Prospectus”	prospectus of the Company dated May 16, 2024
“R&D”	research and development
“RMB”	Renminbi, the lawful currency of the PRC
“RSU”	restricted share unit
“Share(s)”	ordinary share(s) in the share capital of our Company with a par value of US\$0.0005 each
“Shareholder(s)”	holder(s) of our Shares
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“treasury share(s)”	has the meaning ascribed to it under the Listing Rules
“USD” or “US\$”	United States dollars, the lawful currency of the United States
“%”	per cent

By order of the Board
Sunho Biologics, Inc.
Mr. ZHANG Feng
Chairman and executive Director

Hong Kong, August 30, 2024

As of the date of this announcement, the executive Directors are Mr. ZHANG Feng, Dr. YIN Liusong, Ms. JIANG Xiaoling; the non-executive Director is Mr. FAN Rongkui; and the independent non-executive Directors are Mr. CHAN Heung Wing Anthony, Ms. FENG Lan, and Mr. SHI Luwen.

* *English name for identification purpose only.*