FY2023 Financial Results

Company

HEALIOS K.K. (TSE 4593)

Date

February 14, 2024

Important Note on Future Events, etc

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Update
Healios

Three pillars to accelerate monetization

New focus area（P.3）

Medical Materials	Bone marrow-derived cells	iPS cells
HLCM051 Culture Supernatant Universal Donor Cell iPS cell lines, etc.	ARDS (P.6) P2/3 start in Japan (P.16) P2/3 preparation in the US Ischemic stroke (P.7) Japan-U.S. integrated analysis and protocol finalization	Immuno-Oncology iPSC-derived, gene-engineered NK cells
Secure Profitability in the short term Sales target FY2024: 1.0B Yen FY2025: 1.5B Yen	Business scale expansion by securing Global Rights (P.5) Proceed with a combination of Partnering (P.4), carve-outs, and grants	

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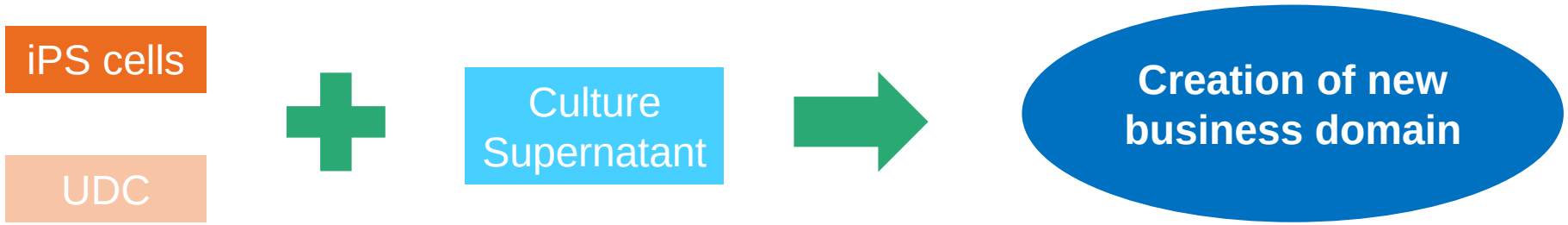
Utilization of medical materials generated during the production of regenerative medical products

- Signed a LOI with AND medical group, a general incorporated association, for joint research to develop new therapeutic methods by providing regenerative medicine technology and raw materials (culture supernatant).
- During the term of the agreement, we plan to receive 180 million yen as joint research expenses. (Several other companies have approached us).
- Aiming to strengthen our financial position as well as effectively use resources by increasing sales as soon as possible.
- Culture supernatant carries a market price of 30,000 yen per 1 cc, and approximately 100L can be produced in one GMP production run (2 weeks) in Healios.

Future business domains



Aim to achieve profitability through the creation of new business domains while focusing on the development of regenerative medical products, our core business.

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New Healios

Accumulation of License Agreements and Development Financing

○ARDS Japan: FY2024 Q2 Target

LOI in the amount of 25 billion yen, including upfront payment and milestone payments, has been signed with Nobelpharma Co., Ltd.

Finalizing definitive terms and conditions (receipt of up front payment)

○ARDS Asia: FY2024 Q3 Target

Aim to enter deals in other Asian countries, building on the deal in Japan.

○ARDS U.S.A.: FY2024 Q3 Target

Peak sales are expected to be in the 300 - 500 billion yen range. Advance project finance, subsidiary finance, etc. with investors. Aim for FDA clearance of Global ARDS P2/3 Study IND and subsidiary financing completion.

○BBG Japan: FY2025 Q1 Scheduled

Expect milestone receipt with approval of BBG - ophthalmic surgical adjuvant (Amount not disclosed, with earnings impact) (P.19)

Execute on a business model that is reasonable at the current market capitalization, and achieve high growth by steadily advancing the ARDS clinical trial progress, the Japan-US data analysis of ischemic stroke, and the progress of eNK.

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Athersys files for bankruptcy proceedings - Healios seeks to acquire assets

- Athersys, with which Healios has an exclusive license agreement for the development, manufacture and marketing of cell therapy products in Japan and some other countries, filed for Chapter 11 bankruptcy protection on January 8, 2024 (U.S. time).

＜Flow of Asset Acquisition＞

- Executed, with court approval, a Debtor-in-Possession financing agreement (the “DIP loan”) with Athersys under Section 363 of the U.S. Bankruptcy Code and obtained a senior lien on their assets.
- Loans financed in the amount of US$2.25 million.
- Court approval of the bidding process and the DIP Loan, whereby Healios became the sole secured creditor of Athersys and the “stalking-horse” bidder for the assets.
- Bidding at auction.
- Finalization of asset purchase targeted for March 2024.

* Healios would take ownership of a patent portfolio that includes over 400 global patents, thereby eliminating future economics that would have otherwise been payable. The acquisition would also provide substantial new global development and partnering opportunities for additional indications.

Note: It has been agreed that Healios’ rights under the agreement with Athersys will be protected under federal law and will be properly managed in this proceeding to ensure that our business is not affected.

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ARDS: Progress of Development and Business

Start of clinical trial

February 2, 2024
Start of Clinical Trial (Phase 2/3) in Japan to confirm efficacy and safety.

- **ProcellCure Inc.**, a consolidated subsidiary of Healios K.K. that promotes the development of the treatment of ARDS, **submitted the notification of Clinical Trial Plan to the PMDA and started the clinical trial**.
- Negotiations with partners, use of public funds, and VC (Saisei Ventures etc.) financing are underway to prepare for patient enrollment.

LOI with Nobelpharma

December 27, 2023

- Letter of Intent signed for development and commercialization of HLCM051 for ARDS in Japan.
- ProcellCure will receive an upfront payment from Nobelpharma under the definitive collaboration agreement. Subsequently, ProcellCure will receive milestone payments upon approval.
- Final products manufactured by ProcellCure are supplied to Nobelpharma.
- In addition to the above, we expect to receive sales milestone payments of approximately 25 billion yen based on our projected sales as of the date of the basic agreement, depending on accumulated sales.
- Nobelpharma agreed to market the product and provide support services for development and regulatory filings as agreed upon.

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Ischemic stroke: Progress of Development and Business

New Healios

Tentative results of the interim analysis

- An interim analysis of the global trial, mainly in the U.S., showed that several hundred more cases were needed to achieve statistical significance in the primary endpoint (mRS shift).
- This number is not particularly large and feasible for the scale of a clinical trial for diseases of the central nervous system. However, **in order to be cautious, we will conduct an analysis of data from a total of more than 400 people in Japan and the U.S. (about 200 people each in country) to determine a design and development policy that can obtain approval in Japan and the U.S. with a high degree of certainty.** (FY2024 Q2-Q3 scheduled)

Concept of Funding for this Project

- **No major costs will be incurred until the analysis of the global clinical trial is completed**.
- Focusing on U.S. investors who can take the risk of late-stage drug development, we will consider mainly project financing and royalty financing by Healios' U.S. subsidiary without equity dilution.

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Issuance of new shares and the 22nd Series of stock acquisition rights by way of third-party allotment

On February 9, Raised approximately 2.16 billion yen through the issuance of new shares and stock acquisition rights.

Stabilize finances by **securing funds for future development and enhancing cash reserves**

Secured funds for the redemption of the 2nd unsecured convertible bond-type bonds with stock acquisition rights of 4 billion yen maturing in July 2024, together with cash on hand to date, **in full**.

If all of the 22nd warrants are exercised at the exercise price, an additional approximately 2.81 billion yen will be secured.

Specific use	Issuance of new shares and warrant	Exercise of warrant	Scheduled expenditure period
①Development funds for HLCM051	–	500M Yen	Feb. 2024 – Dec. 2027
②Research and development fund for eNK cells and next-generation eNK cells	–	500M Yen	Sep.2025 – Dec. 2027
③Bond redemption funds	1.85B Yen	–	Feb. 2024 – Ju. 2024
④Operating funds	Approximately 310M Yen	Approximately 1.81B Yen	Jan. 2025 – Dec. 2027
Total	Approximately 2.16B Yen	Approximately 2.81B Yen	

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Financial Summary

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Consolidated Statement of Income

Update

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R & D expenses for the fiscal year ended December 2023 amounted to ¥2.3 billion (approximately 61% of the previous fiscal year) due to cost reductions. Continue to advance R&D activities while optimizing investment efficiency and expense discipline.

(Units: millions of yen)

	FY2022	FY2023		
			YoY variance	Main reasons for increase/decrease
Revenue	90	121	31	
Operating profit	-5,179	-3,379	1,800	Decrease in SG&A expenses ＋265 Decrease in R&D expenses +1,503
Profit	-5,170	-3,813	1,357	Increase in finance income +110 Increase in finance costs -204 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	3,808	2,304	-1,503	
Number of employees	70	**61**	-9	

(Note)
* For details of the financial figures, please refer to the summary of the financial results announced today.

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Supplemental Explanation of Finance Income and Finance Costs

Update

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Details of finance income and finance costs

In the fiscal year ended December 31, 2023, we recorded finance income of ¥456 million and finance costs of ¥704 million.

Finance income was mainly due to the recording of ¥308 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund [*1], ¥ 73 million in foreign exchange gains and ¥ 50 million in gain on measurement of securities.

Finance costs were mainly due to the recording of 542 million in loss on measurement of derivatives, ¥111 million in interest expenses on bonds[*2] and ¥35 million in interest expenses.

*1. Profit or loss transferred to equity interests held by external investors in the Saisei Fund

Profit or loss transferred to equity interests held by external investors in the Saisei Fund is the transfer amount of profits and losses of Saisei Bioventures, L.P., the consolidated subsidiary of our company, to limited partners other than our company. Saisei Bioventures, L.P. is a limited partnership established by Saisei Capital Ltd., the general partner and consolidated subsidiary of our company.

*2. Interest expenses on bonds

Of the total interest on bonds of 111 million yen posted in the fiscal year ended December 31, 2023, 71 million yen was charged to income using the amortized cost method. This is a non-cash expense recorded in accordance with the International Financial Reporting Standards (IFRS), which was introduced in the 1st quarter of the fiscal year ended December 2020.

Under JGAAP, convertible bond issuances were accounted for as liabilities and issue fees were accounted for as expenses. Under IFRS, however, proceeds, after deducting issue fees from convertible bond issuances, are accounted for as liabilities and equity, based on a certain standard. As a result, the difference between the face value of convertible bonds and the amount recorded as liabilities is amortized (expensed) over the period.

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Consolidated Statement of Financial Position

Update

Healios

(Units: millions of yen)

		December 31, 2022	December 31, 2023		
				Variance	Main reasons for increase/decrease
	Current assets	8,462 (56.3%)	7,683 (50.7%)	▲779	Decrease in cash and cash equivalents -524 (Cash and cash equivalent balance at 12/31/23 was 6,722)
	Non-current assets	6,571 (43.7%)	7,471 (49.3%)	901	Increase in other financial assets +1,251
Total assets		15,033 (100.0%)	15,155 (100.0%)	122	
	Current liabilities	3,808 (25.3%)	5,169 (34.1%)	1,361	Transfer of convertible bonds to current class +3,958 Repayments of borrowings -3,000
	Non-current liabilities	6,842 (45.5%)	6,118 (40.4%)	▲724	Transfer of convertible bonds to current class due to redemption within 1 year -3,887 Proceeds from new borrowings +450 Increase in equity interests held by external investors in Saisei Fund +2,685
Total liabilities		10,650 (70.8%)	11,287 (74.5%)	637	
Total equity		4,382 (29.2%)	3,867 (25.5%)	▲515	Issuance of new shares +2,976 Recording of loss -3,813
Total liabilities and equity		15,033 (100.0%)	15,155 (100.0%)	122	

(Note) * For details of the financial figures, please refer to the summary of the financial results announced today.

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Business Overview

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Pipeline

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	Development Code	Therapeutic Area	Therapy	Region	Discovery	Pre-Clinical	Clinical	Comments
Inflammatory Conditions	HLCM051	Ischemic stroke	MultiStem®	Global		Phase 2/3 (Japan)		Started clinical trial in Japan Global clinical trial under consideration Orphan designation Developing Entity: ProcellCure Inc.
	HLCM051	ARDS	MultiStem®	Japan			Phase 2/3	Awaiting further analysis of the global clinical trial and will consider future action SAKIGAKE designation
Immuno-Oncology	HLCN061	Solid tumors	eNK	Global				Pre-IND started IND: 2025 planned
	–		CAR-eNK	Global				
Replacement Therapies	HLCR011	RPE tear AMD	RPE	Japan			Phase 1/2	Scheduled to be launched in FY2025 (planned by Sumitomo Pharma) Developing Entity: Sumitomo Pharma Co., Ltd.
	–	Retinal disease	UDC-photoreceptors & RPE*	Global				
	HLCL041	Liver disease	Liver buds	Global				Carve-out plan to accelerate R&D and efficiently advance the program
	–	Diabetes	UDC-pancreatic islets	Global				

* Future migration to UDC platform

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HLCM051 ARDS: Development status

Update

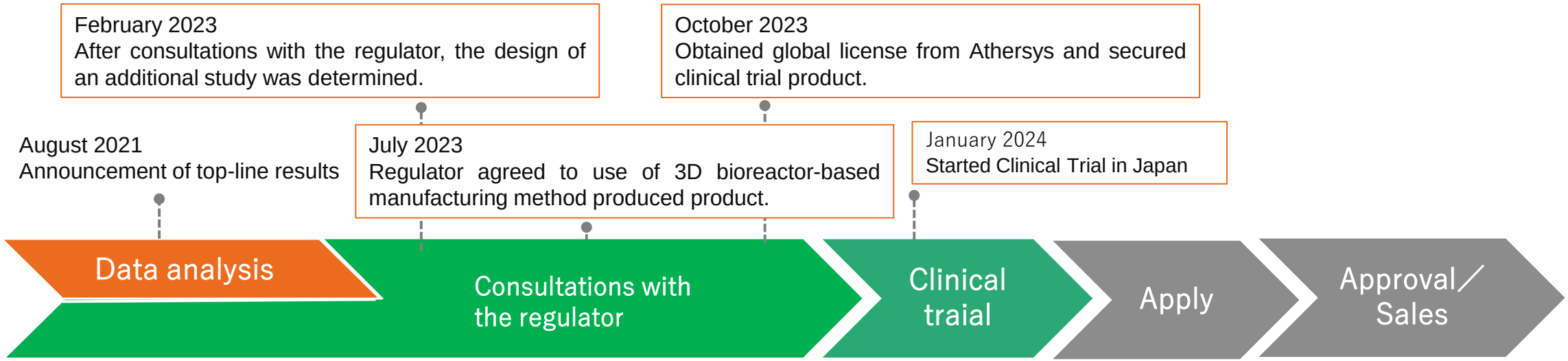
Development plan

Inflammatory Conditions

Final clinical trial started

ARDS

- **ProcellCure Inc. submitted the notification of Clinical Trial Plan to start the clinical trial (Phase 2/3) in Japan and was accepted.**
- **Obtained global license and secured clinical trial product.**



HLCM051 has been designated as an **orphan regenerative medicine product** for use in the treatment of ARDS by the Ministry of Health, Labor and Welfare. (It has received SAKIGAKE status for ischemic stroke.)

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Next Clinical Trial for HLCM051 for ARDS

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Conditions	Placebo-Controlled, Double-Blind, Randomized
Subjects	Patients with pneumonia-induced ARDS *Including patients with pneumonia-induced ARDS caused by COVID-19
Enrollment	80 (HLCM051 [n=40], placebo [n=40])
Primary Endpoint	VFD (the number of days out of 28 during which a ventilator was not used for the patient)
Secondary Endpoint (examples)	Mortality (180 days after administration)

Future Business Policy of ARDS (P.4)

- Japan: Aim for early approval through ProcellCure Inc.
- the U.S.: Aim at FDA clearance of Global ARDS P2/3 Study IND and subsidiary financing completion.
- Asia (China etc.): Consider licensing in consideration of local regulations.

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HLCM051 Ischemic stroke: Development status

Update

Healios

TREASURE study

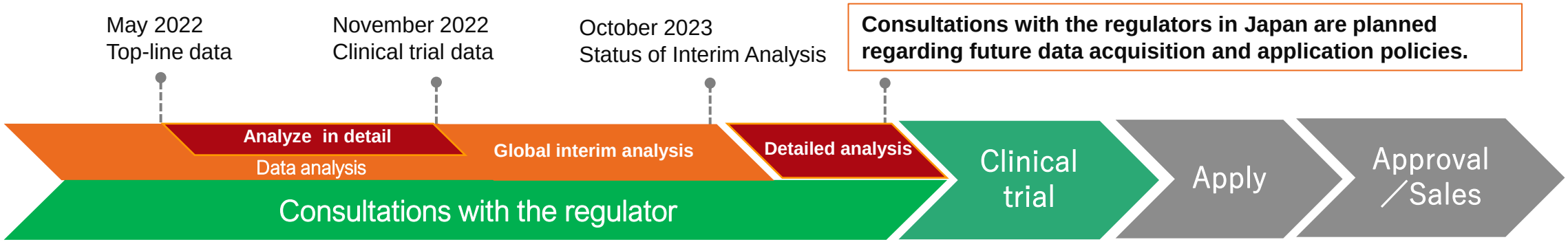
Inflammatory Conditions

Ischemic stroke

No major costs will be incurred until the analysis of the global clinical trial is completed.

Based on the results of further data analysis on the interim analysis*2 of the global clinical trial*1, we will conduct an analysis of data from a total of more than 400 people in Japan and the U.S. (about 200 people each in country) to determine a design and development policy that can obtain approval in Japan and the U.S. with a high degree of certainty.

***1 An analysis performed by an independent statistician during the course of a clinical trial. The results can be used to redefine the number of patients required.**
***2 A phase III study for stroke in the U.S conducted by Athersys. (MASTERS-2 study)**



HLCM051 is designated for SAKIGAKE Designation System

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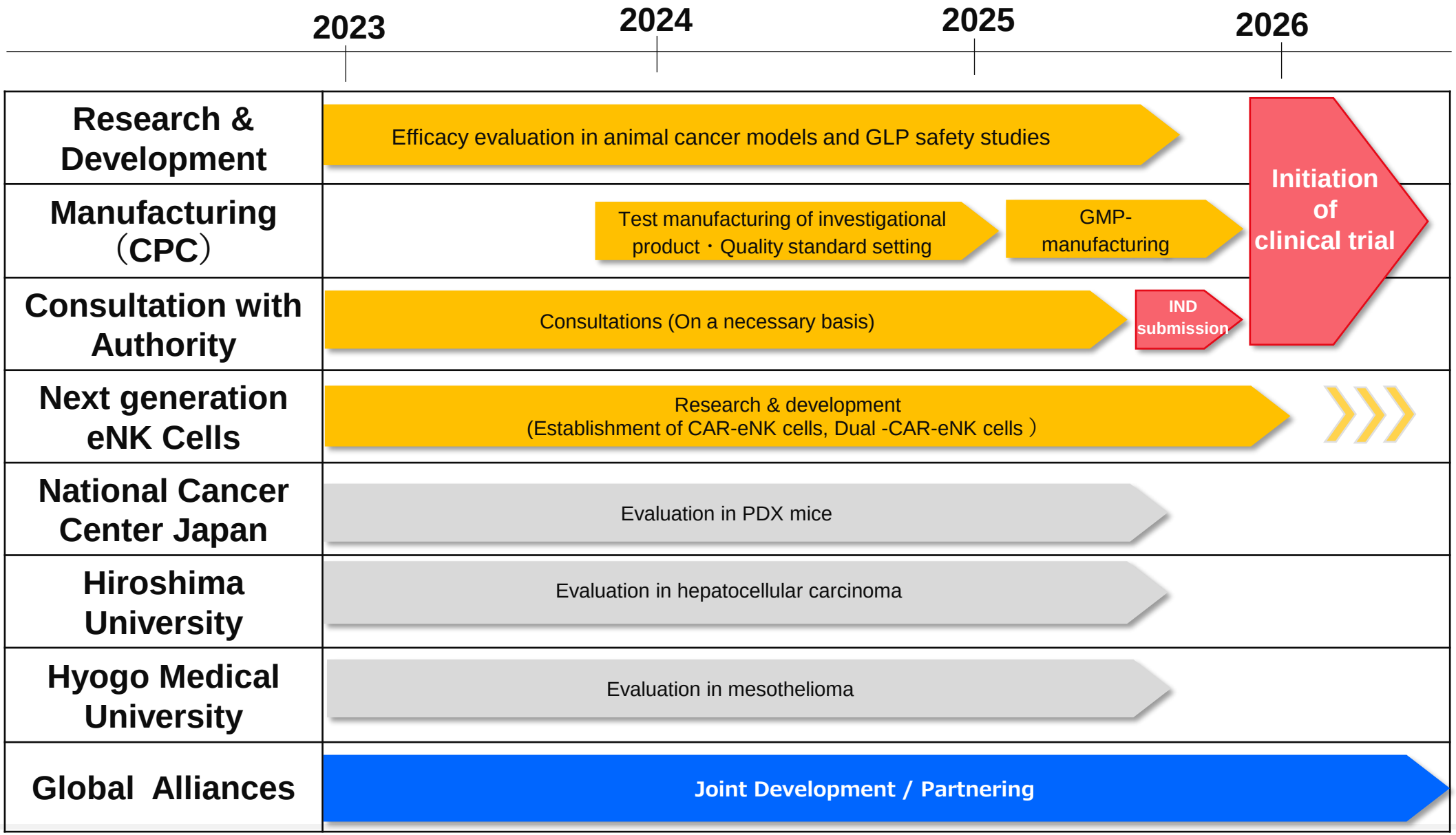
R&D Roadmap of eNK Cells (HLCN061)



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Potential for Future Milestone Income

May 12, 2017, 1st Quarter Financial Results Briefing (page 7)

Compounds	BBG		Transfer our business relating to an ophthalmic surgical adjuvant containing BBG250

[The transferee] D. Western Therapeutics Institute, Inc.
[Transfer price] A lump sum fee of 1.3 billion yen at the time of transfer.

There is also the possibility of receiving milestone payments in line with the progress, etc., of development and out-licensing operations.

[Business transfer due date] April 30, 2017

Expected to receive milestone payments (amount undisclosed) as progress in development is expected in the medium term.

※February 13, 2023, D. Western Therapeutics Institute, Inc. “事業計画及び成長可能性に関する事項”(page.57 Japanese only)

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