



Financial results for the fiscal year ended December 31, 2025

February 16, 2026

Heartseed Inc. (TSE Growth Market: 219A)

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- **Overview of financial results for FY2025**
- **Financial results forecast of FY2026**
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- **Q&A**

Overview of financial results for FY2025

P/L for FY2025

Net sales: Received milestone revenues of 1,919 million yen in Q2 and 1,107 million yen in Q4 under the global collaboration and license agreement w/ Novo Nordisk prior to the termination of the partnership.

SG&A: Increased due to the 14-month fiscal year and upfront investments. Some expenses accelerated by faster-than-expected HS-005 trial preparations.

Profit: The YoY increase in clinical trial expenses due to the full-scale LAPiS trial for HS-001 was offset by milestone revenue.

(The amount in yen are rounded off to millions)

(Millions of yen)	FY2024 results* ¹ (12 months)	FY2025 results* ¹ (14 months)	FY2025 forecast* ²	Progress
Net sales	873	3,026	3,027	100.0%
Gross profit	873	3,026	-	
SGA expenses	1,912	2,754	-	
Operating profit	(1,038)	272	311	87.5%
Ordinary profit	(818)	288	328	88.1%
Profit	(812)	190	229	83.2%

*1: Due to the change in fiscal year-end, the fiscal year ending December 2025 (Nov 1, 2024 - Dec 31, 2025) is an irregular 14-month period.

Accordingly, the percentage change compared to the previous fiscal year (Nov 1, 2023 - Oct 31, 2024) are not presented.

*2: The financial results forecast was revised on December 11, 2025.



B/S for FY2025

Overall: Cash and deposits accounted for approx. 96% of total assets of 7,675 million yen, maintaining a robust B/S.

Assets & liabilities: Established high level of financial soundness with small fixed assets and no interest-bearing debt through asset-light management.

Cash and deposits: In good position where the company can firmly accelerate its activities for commercialization of HS-001 and the upcoming clinical trial for HS-005, both in Japan.

(The amount in yen are rounded off to millions)

(Millions of yen)	FY2024 (As of Oct 31, 2024) (A)	FY2025 (As of Dec 31, 2025) (B)	Difference (B-A)
Current assets	6,403	7,143	739
Cash and deposits	5,297	6,836	1,538
Non-current assets	663	532	(131)
Total assets	7,067	7,675	608
Current liabilities	282	320	38
Non-current liabilities	162	160	(1)
Total liabilities	444	480	36
Total net assets	6,623	7,194	571
Total liabilities and net assets	7,067	7,675	608



Business progress in FY2025

HS-001: All 10 patients have been administered. Following presentations at domestic and international academic conferences by clinical trial sites/Heartseed, the company announced interim data (low-dose: 1-yr / high-dose: 6-mo). On track for the application for approval in 2026 and the commercial launch in 2027.

HS-005: Released the new partner for delivery catheter system. The patient recruitment activities are underway for the EMERALD study in Japan.

Product pipeline	FY2025 goals	Progress in FY2025
Overview	—	<ul style="list-style-type: none"> Almost completed the transfer of technical data and know-how from Novo Nordisk.
HS-001 (In conjunction w/ CABG) 	<ul style="list-style-type: none"> Complete the administration of the last case of the LAPIs Study (4 out of a total of 5 high-dose cohort cases have been completed). Continue to post-trial follow-up and prepare for application for approval. (The latest clinical data may be presented by the investigators of clinical trial sites at academic conference, etc.) 	<ul style="list-style-type: none"> LAPIs study is currently in the follow-up period; preparation of the application for approval is on track. Following presentations by physicians at clinical trial sites at domestic conferences and company presentations at international conferences such as the American Heart Association, the company presented favorable interim data for all 10 patients. (low-dose: 1-yr / high-dose: 6-mo)
HS-005 (Catheter administration) 	<ul style="list-style-type: none"> To meet the diverse needs of the market, we will pursue co-development of catheter with Novo Nordisk and new partners. The main goal is to finalize the Japan clinical trial design with the authorities and submit the clinical trial notification within 2025. 	<ul style="list-style-type: none"> Announced the collaboration and partnership with Japan Lifeline Co., Ltd. for delivery catheter system. Completion of the 30-day review of the Clinical Trial Notification for the EMERALD study. The patient recruitment activities have started for the first-patient-dosing estimated in the H1 of 2026.
HS-040 (Autologous iPS cell-derived cardiomyocyte spheroids)	<ul style="list-style-type: none"> Continue to accumulate knowledge and know-how on autologous cell technologies, while utilizing support from AMED-subsidized projects. 	<ul style="list-style-type: none"> Basic and pre-clinical development progressed under the support of AMED.



Financial Results Forecast for FY2026

Forecast for FY2026

Net sales: The expected amount of a milestone payment newly approved was recognized, following discussions with Novo Nordisk regarding the transition and contract termination.

SG&A: Steady execution of upfront investments for business progress, including R&D expenses for HS-005 clinical trials and preparations for HS-001 commercial launch.

Net income: Balancing upfront investment and expenses control to achieve early commercialization starting in Japan, under a stable financial position.

(The amount in yen are rounded off to millions)

(Millions of yen)	FY2025 Forecast* ¹ (14 months) (A)	FY2026 Forecast (12 months) (B)	YoY (B-A) / A
Net sales	3,026	451	-85.1%
Gross profit	3,026	451	-85.1%
SG&A expenses	2,754	2,658	-3.5%
Operating income	272	(2,207)	-
Ordinary income	288	(2,155)	-
Net income	190	(2,158)	-

*1: Due to the change in fiscal year-end, the fiscal year ending December 2025 (Nov 1, 2024 - Dec 31, 2025) is an irregular 14-month period.

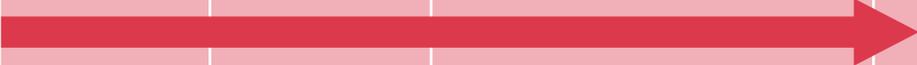
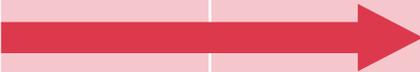
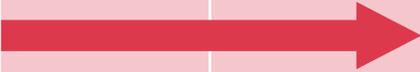
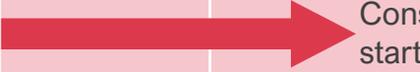


FY2026 goals for main pipeline

Product pipeline	FY2026 Goals
Overview	<ul style="list-style-type: none">Leverage a favorable negotiation position supported by robust scientific evidence to establish a mid- to long-term global strategy.
<p>HS-001 (In conjunction w/ CABG)</p> 	<ul style="list-style-type: none">Complete data compilation for all 10 cases in the LAPiS study and target an application for approval within 2026.Advance preparations for the infrastructure toward sales launch in 2027.
<p>HS-005 (Catheter administration)</p> 	<ul style="list-style-type: none">Through collaboration with clinical trial sites, aim to initiate first-patient dosing in the EMERALD study in the first half of 2026.Following approval by the Safety Monitoring Committee, explore opportunities for conference presentations by physicians at the trial sites and/or Heartseed.
<p>HS-040 (Autologous iPS cell-derived cardiomyocyte spheroids)</p>	<ul style="list-style-type: none">Continue to accumulate knowledge and know-how on autologous cell technologies, while utilizing support from AMED-subsidized projects.



Product pipeline

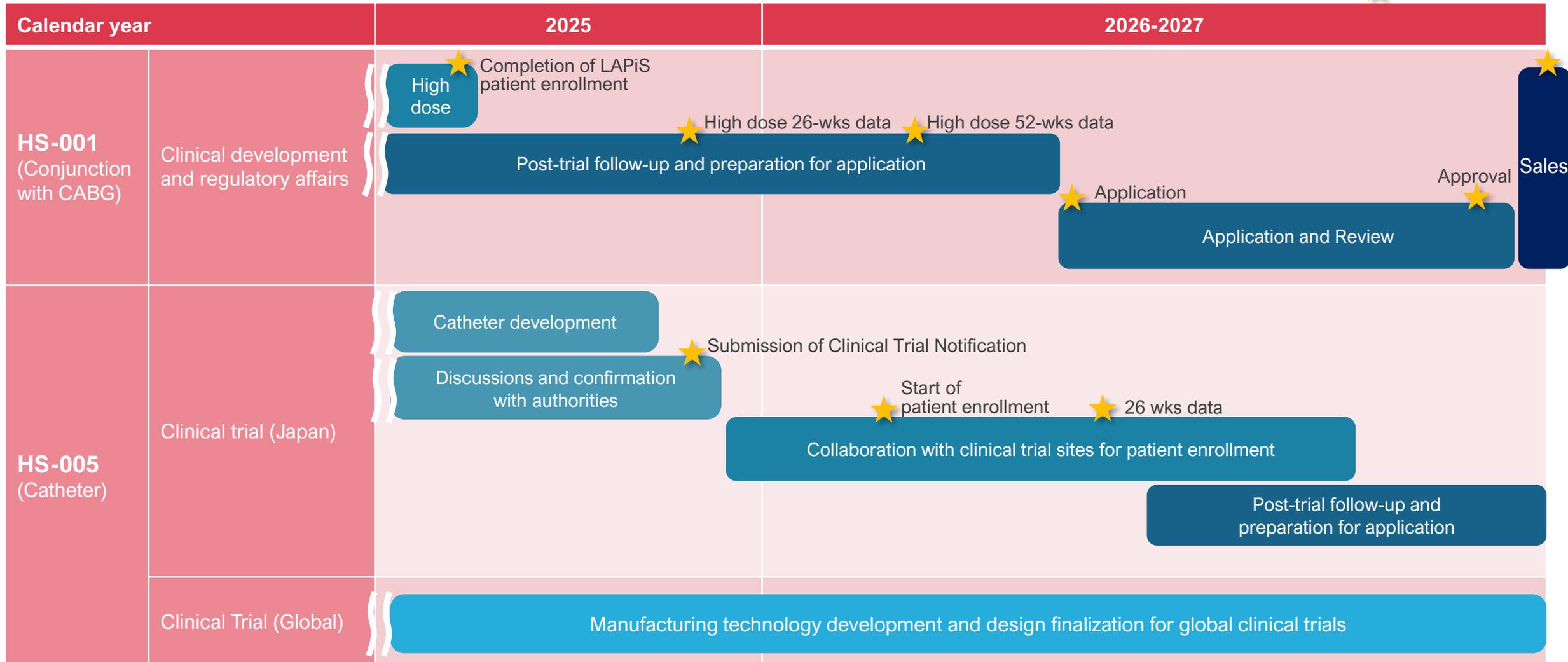
Code	Cell type	Administration	Indication	Region	Research	Pre-clinical	Clinical trial	Application for approval
HS-001	Allogeneic iPSC-derived cardiomyocyte spheroids	Open heart surgery (In conjunction with CABG) 	IHD* ¹	Japan	 LAPiS study (Phase1/2)			
HS-005	Allogeneic iPSC-derived cardiomyocyte spheroids	Catheter 	IHD	Japan	 EMERALD study (Phase1/2)			
			DCM* ²	Japan	 Completion of the review for clinical trial; preparations are underway to initiate the trial in 2026			
			IHD	Overseas	 Consultation with authorities started in 2023			
HS-040	Autologous iPSC-derived cardiomyocyte spheroids	In conjunction with open heart surgery / catheter	-	TBD	 AMED grants accelerate development			

*1: Heart failure due to ischemic heart disease *2: Heart failure due to dilated cardiomyopathy



Major milestones targets for HS-001 and HS-005 (as of February 13, 2026)

★ Significant events



Note: This is only a projected schedule and does not guarantee that it will be realized in this timeframe.



Conferences being explored for presentation opportunities in 2026

Explore presentation opportunities to enhance awareness and understanding of HS-001 and HS-005 within the academic community.

* Presentations at the conferences listed below are not guaranteed at this stage.

Mar Apr May Jun Jul Aug Sep Oct Nov Dec

Domestic conferences



The 25th Annual Meeting of the Japanese Society for Regenerative Medicine
Mar 19 – Mar 20



The 90th Annual Scientific Meeting of the Japanese Circulation Society
Mar 20 – Mar 22



The 30th Annual Scientific Meeting of the Japanese Association for Coronary Artery Surgery
Jul 16 – Jul 17



The 74th Annual Meeting of the Japanese College of Cardiology
Sep 11 – Sep 13



The 66th Annual Scientific Meeting of the Japanese Society of Nuclear Medicine
Nov 19 – Nov 21



The 30th Annual Scientific Meeting of the Japanese Heart Failure Society
Oct 23 – Oct 25

International conferences



ISCT Cell & Gene Therapy Annual Meeting 2026
May 6 – May 9



European Society of Cardiology
Aug 28 – Aug 31



International Society for Stem Cell Research: iPSC 20th Anniversary Symposium
Oct 20 – Oct 22



JSRM-ISCT Joint International Conference on iPSCs 2026
Mar 21



CVBE Symposium 2026
Jun 18 – Jun 20



ISSCR 2026
Jul 8 – Jul 11



American Heart Association Scientific Sessions 2026
Nov 7 – Nov 9



Recent Topics

Steady external communications to enhance our global academic presence

2025 Sep

Oct

Nov

Dec

2026 Jan

Case report by clinical trial sites at domestic conferences



The 73rd Annual Scientific Meeting of the Japanese Circulation Society



The 29th Annual Scientific Meeting Japanese Heart Failure Society



The 65th Annual Scientific Meeting of the Japanese Society of Nuclear Medicine

Clinical trial progress presented by Heartseed at international conferences

Summary data from the low-dose cohort and case reports from the high-dose cohort



9th International Forum On Medical Innovation of Cell & Bio Therapy



American Heart Association



Summit on the Translation of PSC-Derived Cardiac Therapies

Presentations of clinical trial progress at a prestigious international conference

All 10 cases (low-dose: 1-yr; high-dose: 6-mo)

KEYSTONE SYMPOSIA

Keystone Symposia

“iPSCs: Progress, Opportunities, and Challenges”



Invited to a prestigious conference as a company nearing application

At the Keystone Symposia conference marking the 20th anniversary of the iPS cell discovery, Heartseed presented progress in its cardiac regenerative therapy, drawing interest from experts worldwide as it advances toward clinical application.

January 28, 2026, Kyoto



Image provided by the Center for iPS Cell Research and Application (CiRA), Kyoto University



HS-005: Progressing smoothly toward FIH in the first half of 2026

Heartseed announced the completion of the PMDA's 30-day review for the Phase I/II EMERALD study of HS-005 (catheter administration) on Nov 4, 2025, enabling the initiation of the trial in Japan. The patient recruitment activities have been kicked-off.

Overview of the EMERALD study design

7 patients with heart failure caused by **ischemic heart diseases**

Administration of 150 million cardiomyocytes



7 patients with heart failure caused by **dilated cardiomyopathy**

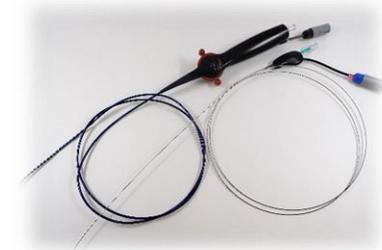
Administration of 150 million cardiomyocytes



26-week
Safety and efficacy
confirmation

52-week
Safety and efficacy
confirmation

- **Primary endpoint:** Safety at 26 weeks
- **Secondary endpoints:** Safety at 52 weeks, Efficacy at 26 and 52 weeks
 - Local myocardial wall motion
 - Reduced cardiac enlargement (LVEDV, CTR)
 - Improved cardiac function and biomarkers (NYHA, LVEF, NT-proBNP)
- **Immunosuppressants:** Steroids, MMF, and tacrolimus post-transplant; with tacrolimus alone after Week 26.



Delivery catheter system

● **SMC (Safety Monitoring Committee)**

An independent committee composed of cardiology experts that reviews and evaluates the appropriateness of continuing the clinical trial



A close-up photograph of two hands, one slightly larger than the other, gently cupping a bright red, glossy heart. The hands are positioned in the center of the frame, with the fingers slightly curled around the heart. The background is a light-colored, textured surface, possibly wood or stone, with some darker spots. The overall tone is warm and caring.

Open the Door to the Treatment of Heart Disease through Regenerative Medicine

Our mission is to deliver “Remuscularization” therapy to patients with heart failure, which is considered difficult to cure, and to open the door to treatment of heart disease through regenerative medicine.

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