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November 13, 2026

Non-consolidated Financial Results for the Nine Months Ended September 30, 2026 (Under Japanese GAAP)

Company name: Heartseed Inc.
Listing: Tokyo Stock Exchange
Securities code: 219A
URL: https://heartseed.jp/
Representative: Keiichi Fukuda, MD/PhD/FACC, CEO, Representative Director of the Board
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Scheduled date to commence dividend payments: –
Preparation of supplementary material on financial results: Yes
Holding of financial results briefing: Yes, for institutional investors & analysts

(Yen amounts are rounded down to millions, unless otherwise noted.)

1. Non-consolidated financial results for the nine months ended September 30, 2026 (from January 1, 2026 to September 30, 2026)

(1) Non-consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit	
Nine months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
September 30, 2026	467	–	(1,131)	–	(1,058)	–	(1,062)	–
July 31, 2025	1,919	–	351	–	304	–	243	–

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2026	(46.44)	–
July 31, 2025	10.84	10.58

Notes: 1. Diluted earnings per share for the nine months ended September 30, 2026 is not stated in the above table because, although there are potential shares, basic loss per share was recorded.
2. The fiscal year-end date was changed from the fiscal year ended December 31, 2025, resulting in a 14-month accounting period from November 1, 2024 to December 31, 2025. Consequently, because the comparative periods differ between the previous nine months (from November 1, 2024 to July 31, 2025) and the current nine months (from January 1, 2026 to September 30, 2026), the year-on-year percentage changes for the nine-month period are not presented.

(2) Non-consolidated financial position

	Total assets	Net assets	Equity-to-asset ratio
As of	Millions of yen	Millions of yen	%
September 30, 2026	7,017	6,177	88.0
December 31, 2025	7,675	7,194	93.7

Reference: Shareholder's Equity
As of September 30, 2026: ¥6,173 million
As of December 31, 2025: ¥7,190 million

2. Cash dividends

	Annual dividends per share					
	First quarter-end	Second quarter-end	Third quarter-end	Fourth quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2025	–	–	–	–	0.00	0.00
Fiscal year ending December 31, 2026	–	–	–			
Fiscal year ending December 31, 2026 (Forecast)				–	0.00	0.00

Note: Revisions to the forecast of cash dividends most recently announced: None

3. Forecast of non-consolidated financial results for the fiscal year ending December 31, 2026 (from January 1, 2026 to December 31, 2026)

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Fiscal year ending December 31, 2026	467	–	(2,207)	–	(2,155)	–	(2,158)	–	(94.44)

Notes: 1. Revisions to the earnings forecasts most recently announced: None
2. The percentage change compared to the previous period has been omitted, since the fiscal year ended December 31, 2025 is an irregular 14-month period due to the changes in the fiscal year-end.

*** Notes**

(1) Adoption of accounting treatment specific to the preparation of quarterly non-consolidated financial statements: None

(2) Changes in accounting policies, changes in accounting estimates, and restatement

(i) Changes in accounting policies due to revisions to accounting standards and other regulations: None

(ii) Changes in accounting policies due to other reasons: None

(iii) Changes in accounting estimates: None

(iv) Restatement: None

(3) Number of issued shares (ordinary shares)

(i) Total number of issued shares at the end of the period (including treasury shares)

As of September 30, 2026	22,929,400 shares
As of December 31, 2025	22,858,200 shares

(ii) Number of treasury shares at the end of the period

As of September 30, 2026	– shares
As of December 31, 2025	– shares

(iii) Average number of shares outstanding during the period (cumulative from the beginning of the fiscal year)

Nine months ended September 30, 2026	22,882,428 shares
Nine months ended July 31, 2025	22,458,766 shares

* Review of the Japanese-language originals of the attached quarterly non-consolidated financial statements by certified public accountants or an audit firm: None

* Proper use of earnings forecasts, and other special matters

Cautionary notice on forward-looking information

The financial results forecasts and other forward-looking information contained in this document are based on the information currently available to the Company and certain assumptions considered reasonable by the Company. It is not a guarantee that the forecasts will be achieved, and actual results may differ significantly from such forecasts depending on various factors. For more information on the financial results forecast, please refer to page 3 of the Attachment, “1. Quarterly Financial Results for the Fiscal Year Under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information.”

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1. Quarterly Financial Results for the Fiscal Year Under Review

The Company changed the fiscal year-end date from the fiscal year ended December 31, 2025, resulting in a 14-month accounting period from November 1, 2024 to December 31, 2025. Consequently, because the comparative periods differ between the previous nine months (from November 1, 2024 to July 31, 2025) and the current nine months (from January 1, 2026 to September 30, 2026), the year-on-year percentage changes for the nine-month period are not presented.

(1) Explanation of Business Results

During the first nine months of the current fiscal year (from January 1, 2026 to September 30, 2026), the Japanese economy maintained a moderate recovery trend supported by improvements in the employment and income environment. However, outlook remained uncertain due to factors such as developments in U.S. policies and the rising global geopolitical risks, along with the impact of soaring prices caused by the ongoing progression of yen depreciation, as well as fluctuations in financial and capital markets including interest rate trends in Japan and globally.

In the Japanese regenerative medicine industry, the revised Pharmaceutical Affairs Law enacted in 2014 introduced a “conditional and time-limited approval system” for regenerative medical products. Moreover, the “Sakigake designation system” was also enacted in 2019 to shorten the approval review period and provide priority support for prior consultation with the authorities. Thus, in Japan there are systems in place that allow for the rapid commercialization of superior regenerative medical products. Under this regulatory framework, efforts toward the social implementation of regenerative medicine are steadily progressing, as demonstrated by the conditional and time-limited approval granted to some iPS cell-based products in March 2026.

In terms of the overview of the business during the nine months ended September 30, 2026, the Company continued the development of its lead pipeline, the treatment program (HS-001) for heart failure patients with ischemic heart disease by administration of allogeneic iPS cell-derived cardiomyocyte spheroids in conjunction with open heart surgery. In the domestic Phase I/II clinical trial concomitant with coronary artery bypass grafting (LAPiS study), the analysis, including data compilation for all 10 cases and data interpretation by a third-party institution, has been completed. Favorable top-line results up to 52 weeks were presented in an invited lecture at the European Society of Cardiology Congress (ESC Congress 2026).

Regarding the development of catheter-based administration treatment program (HS-005) that is less invasive for patients, the first patient dosing for heart failure caused by dilated cardiomyopathy was conducted in the domestic Phase I/II clinical trial using a catheter delivery system (EMERALD study). Following a safety evaluation by the independent Safety Monitoring Committee, the continuation of the trial for the second and subsequent cases was approved. In response to this, efforts are being made to accelerate patient enrollment for dilated cardiomyopathy and to prepare for the enrollment of the first case of heart failure due to ischemic heart disease.

Furthermore, with a view toward future application for marketing authorization approval as well as domestic commercialization and market launch, an application for a Marketing Authorization Holder License for Regenerative Medical Products was filed with the Tokyo Metropolitan Government, and the license was obtained. Going forward, for HS-001, the Company will focus on consultations with the Pharmaceuticals and Medical Devices Agency (PMDA) toward filing the application for marketing authorization approval, as well as on patient enrollment in the EMERALD study for HS-005.

Under these circumstances, for the nine months ended September 30, 2026, the Company reported net sales of 467,370 thousand yen, operating loss of 1,131,528 thousand yen, ordinary loss of 1,058,242 thousand yen, and net loss of 1,062,711 thousand yen.

As the Company has only one segment, the pharmaceutical business, the description of business results by segment is omitted.

(2) Explanation of Financial Position

Assets

Total assets as of September 30, 2026 decreased by 658,548 thousand yen from the end of the previous fiscal year to 7,017,201 thousand yen. Current assets decreased by 623,873 thousand yen from the end of the previous fiscal year to 6,519,661 thousand yen. This was mainly due to decreases of 601,114 thousand yen in cash and deposits and 78,620 thousand yen in consumption taxes refund receivable. Non-current assets decreased by 34,675 thousand yen from the end of the previous fiscal year to 497,539 thousand yen. This was mainly due to a decrease of 34,675 thousand yen in property, plant and equipment due to the recording of depreciation, etc.

Liabilities

Total liabilities as of September 30, 2026 increased by 358,666 thousand yen from the end of the previous fiscal year to 839,503 thousand yen. Current liabilities increased by 355,050 thousand yen from the end of the previous fiscal year to 675,378 thousand yen. This was mainly due to an increase of 500,000 thousand yen in short-term borrowings, while accounts payable - other decreased by 82,587 thousand yen due to payment, and advances received decreased by 59,845 thousand yen due to the finalization of the subsidy from Japan Agency for Medical Research and Development (AMED). Non-current liabilities increased by 3,616 thousand yen from the end of the previous fiscal year to 164,125 thousand yen. This was mainly due to the recording of provision for share-based payments of 2,185 thousand yen.

Net Assets

Total net assets as of September 30, 2026 decreased by 1,017,215 thousand yen from the end of the previous fiscal year to 6,177,697 thousand yen. This was mainly due to an increase of 1,062,711 thousand yen in accumulated deficit due to the recording of loss.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

There is no change to the earnings forecast for the fiscal year ending December 31, 2026, which was announced on May 15, 2026 in the “Non-consolidated Financial Results for the Three Months Ended March 31, 2026 (Under Japanese GAAP).”

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousands of yen)

	As of December 31, 2025	As of September 30, 2026
Assets		
Current assets		
Cash and deposits	6,836,009	6,234,895
Supplies	47,868	101,384
Advance payments to suppliers	26,125	20,415
Prepaid expenses	45,911	47,239
Accounts receivable - other	3,359	10,085
Consumption taxes refund receivable	184,260	105,640
Total current assets	7,143,534	6,519,661
Non-current assets		
Property, plant and equipment	431,381	396,706
Investments and other assets	100,833	100,833
Total non-current assets	532,214	497,539
Total assets	7,675,749	7,017,201
Liabilities		
Current liabilities		
Short-term borrowings	–	500,000
Lease liabilities	252	–
Accounts payable - other	172,170	89,583
Accrued expenses	32,616	22,224
Income taxes payable	9,181	15,855
Advances received	71,492	11,646
Deposits received	8,601	13,945
Provision for bonuses	26,013	22,124
Total current liabilities	320,328	675,378
Non-current liabilities		
Asset retirement obligations	160,508	161,939
Provision for share-based payments	–	2,185
Total non-current liabilities	160,508	164,125
Total liabilities	480,837	839,503
Net assets		
Shareholders' equity		
Share capital	1,327,698	1,350,905
Capital surplus	8,441,650	8,464,857
Accumulated deficit	(2,579,138)	(3,641,850)
Total shareholders' equity	7,190,210	6,173,912
Stock acquisition rights	4,702	3,785
Total net assets	7,194,912	6,177,697
Total liabilities and net assets	7,675,749	7,017,201

(2) Quarterly Statement of Income

(For the nine months ended September 30, 2026)

(Thousands of yen)

	Nine months ended July 31, 2025	Nine months ended September 30, 2026
Net sales	1,919,350	467,370
Cost of sales	–	–
Gross profit	1,919,350	467,370
Selling, general and administrative expenses	1,568,338	1,598,898
Operating profit (loss)	351,011	(1,131,528)
Non-operating income		
Interest income	1,712	10,576
Foreign exchange gains	–	12,772
Subsidy income	–	52,000
Miscellaneous income	467	559
Total non-operating income	2,180	75,908
Non-operating expenses		
Interest expenses	140	2,622
Foreign exchange losses	48,320	–
Total non-operating expenses	48,461	2,622
Ordinary profit (loss)	304,730	(1,058,242)
Profit (loss) before income taxes	304,730	(1,058,242)
Income taxes - current	63,684	4,469
Income taxes - deferred	(2,404)	–
Total income taxes	61,280	4,469
Profit (loss)	243,450	(1,062,711)

(3) Notes to the Quarterly Financial Statements

Notes on the segment information

As the Company operates in a single operating segment consisting only of the pharmaceutical business, the description by segment is omitted.

Notes in the event of significant changes in shareholders' equity

Not applicable.

Notes on going concern assumptions

Not applicable.

Notes on the quarterly statement of cash flows

The quarterly statement of cash flows for the nine months ended September 30, 2026 was not prepared. Depreciation (including amortization of intangible assets) for the respective periods was as follows:

(Thousands of yen)

	Nine months ended July 31, 2025	Nine months ended September 30, 2026
Depreciation	31,174	35,953