

Translation

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Financial Results for the Three Months Ended January 31, 2025 (Under Japan GAAP) (Non-consolidated)



March 13, 2025

Company name: Heartseed Inc.
 Listing: Tokyo Stock Exchange
 Securities code: 219A
 URL: <https://heartseed.jp/>
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 Scheduled date to commence dividend payments: -
 Preparation of supplementary materials on financial results: No
 Holding of financial results briefings: No (for institutional investors, analysts and financial institutions)

(The amount in yen are rounded off to millions, unless otherwise noted)

1. Financial Results for the Three Months Ended January 31, 2025 (from November 1, 2024 to January 31, 2025)

(1) Operating Results (Cumulative total)

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Income		Ordinary Income		Net Income	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Three months ended								
January 31, 2025	-	-	(485)	-	(478)	-	(478)	-
January 31, 2024	-	-	-	-	-	-	-	-

	Net Income Per Shares	Diluted Net Income Per Shares
	Yen	Yen
Three months ended		
January 31, 2025	(21.52)	-
January 31, 2024	-	-

(Notes)

- Since quarterly financial statements for the three months ended January 31, 2024 were not prepared, the operating results and year-on-year changes for the three months ended January 31, 2024, as well as the year-on-year changes for the three months ended January 31, 2025, are not stated.
- Diluted net income per share for the three months ended January 31, 2025 is not stated in the above table, because net income per share was negative.

(2) Financial Position

	Total Assets	Total Net Assets	Equity Ratio
As of	Millions of yen	Millions of yen	%
January 31, 2025	6,626	6,217	93.7
October 31, 2024	7,067	6,623	93.5

(Reference) Shareholders' equity (millions of yen): 6,206, as of January 31, 2025 and 6,610, as of October 31, 2024

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 October 31, 2024	-	-	-	-	0.00	0.00
Fiscal year ending December 31, 2025	-					
Fiscal year ending December 31, 2025 (Forecast)		-	-	-	0.00	0.00

(Note) Revision to the most recently announced dividend forecast: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2025 (from November 1, 2024 to December 31, 2025)

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Income		Ordinary Income		Net Income		Net Income Per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Fiscal year ending December 31, 2025 (Forecast)	2,394	174.0	(1,010)	-	(958)	-	(959)	-	(43.14)

(Note) Revision to the most recently announced financial results forecast: No

***Notes**

(1) Accounting policies adopted specially for the preparation of quarterly financial statements: No

(2) Changes in accounting policies, changes in accounting estimates, and retrospective restatements

(i) Changes in accounting policies due to revisions of accounting standards: No

(ii) Changes in accounting policies due to reasons other than (i) above: No

(iii) Changes in accounting estimates: No

(iv) Retrospective restatements: No

(3) Number of issued shares (ordinary shares)

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

As of January 31, 2025	22,346,200 shares
As of October 31, 2024	22,225,400 shares

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

As of January 31, 2025	- shares
As of October 31, 2024	- shares

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

Three months ended January 31, 2025	22,245,452 shares
Three months ended January 31, 2024	- shares

(Note) Since quarterly financial statements for the three months ended January 31, 2024 were not prepared, the “Average number of issued shares during the period” for the three months ended January 31, 2024 is not stated.

*These quarterly financial results are outside the scope of quarterly reviews by certified public accountants or audit firms.

*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. Qualitative Information on Quarterly Financial Results for the Period under Review: (3) Explanation of Financial Results Forecast and Other Forward-looking Information.”

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1. Qualitative Information on Financial Results for the Fiscal Year under Review

(1) Explanation of Business Results

During the first three months of the current fiscal year (November 1, 2024 to January 31, 2025), the Japanese economy showed signs of gradual improvement due to strong inbound demand and enhancement in the employment and income environment. However, there are some uncertainties with the domestic economy due to factors such as fluctuations in financial and capital markets, as well as the U.S. policy trend and unstable international conditions.

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.

In terms of the overview of our business during the three months ended January 31, 2025, the Company continued development of our lead pipeline. This is a treatment program (HS-001) for heart failure patients with ischemic heart disease by administration of allogeneic iPS cell-derived cardiomyocytes spheroids in conjunction with open heart surgery. In the ongoing Phase I/II clinical trial (LAPiS study) in combination with coronary artery bypass graft surgery, which was scheduled to enroll a total of 10 patients (5 patients in the low-dose cohort and 5 patients in the high dose cohort), the administration of the final patient was completed in this first quarter of the fiscal year.

Meanwhile, for the development of catheter-based administration method that is less invasive for patients, under an exclusive worldwide collaboration and license agreement with Novo Nordisk A/S, a leading global pharmaceutical company, we are aiming to submit a clinical trial notification in Japan by the end of 2025. Currently, we are confirming and verifying the method with a prototype product. In addition, to meet the diverse needs of the market, we are also working on the joint development of a catheter with another new partner.

As a result, the Company reported operating losses of 485,358 thousand yen, ordinary losses of 478,245 thousand yen, and net losses of 478,696 thousand yen in the three month period ended January 31, 2025.

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

(2) Explanation of Financial Position

1) Assets, Liabilities and Equity

(Assets)

Total assets at the end of the three months ended January 31, 2025 decreased by 441,432 thousand yen from the end of the previous fiscal year to 6,626,161 thousand yen. Current assets decreased by 434,583 thousand yen to 5,969,231 thousand yen. This is mainly due to a 768,250 thousand yen decrease in accounts receivable from its cash collection as well as a 376,362 increase in cash and cash equivalents. Non-current assets decreased by 6,849 thousand yen to 656,930 thousand yen. This is mainly due to a 6,849 thousand yen decrease in property, plant and equipment by recording depreciation.

(Liabilities)

Total liabilities at the end of the three months ended January 31, 2025 decreased by 35,394 thousand yen from the end of the previous fiscal year to 408,949 thousand yen. Current liabilities decreased by 34,306 thousand yen to 247,767 thousand yen. This is mainly due to a 13,000 thousand yen increase in advances of subsidies received from the Japan Agency for Medical Research and Development (AMED) while there was also a decrease by 40,596 thousand yen in income taxes payable due to the payment. Non-current liabilities decreased by 1,087 thousand yen to 161,181 thousand yen. This is mainly due to a 801 thousand yen decrease by reversal of deferred tax liabilities and a 755 thousand yen decrease by reversal of lease obligations.

(Net Assets)

Total net assets at the end of the three months ended January 31, 2025 decreased by 406,037 thousand yen from the end of the previous fiscal year to 6,217,212 thousand yen. This is mainly due to a 478,696 thousand yen decrease in retained earnings from the net losses.

(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, 2025, which was announced on December 23, 2024 in the “Notice Regarding the Revision of Full-Year Financial Results Forecast due to Change in Fiscal Year-End” (Japanese language only release).

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousands of yen)

	FY2024 (As of October 31, 2024)	FY2025 (As of January 31, 2025)
Assets		
Current assets		
Cash and deposits	5,297,166	5,673,529
Account receivable	768,250	-
Supplies	86,336	63,726
Advance payments to suppliers	42,571	15,505
Prepaid expenses	40,656	32,508
Accounts receivable: other	30,060	3,127
Consumption taxes refund receivable	138,774	168,522
Income taxes refund receivable	-	12,312
Total current assets	6,403,814	5,969,231
Non-current assets		
Property, plant and equipment	455,707	448,858
Investments and other assets	208,072	208,072
Total non-current assets	663,779	656,930
Total assets	7,067,594	6,626,161
Liabilities		
Current liabilities		
Lease liabilities	4,638	4,291
Accounts payable: other	80,828	88,597
Accrued expenses	37,439	30,922
Income taxes payable	54,258	13,661
Advances received	77,989	90,989
Deposits received	18,916	11,302
Asset retirement obligations	8,003	8,002
Total current liabilities	282,074	247,767
Non-current liabilities		
Lease liabilities	755	-
Asset retirement obligations	158,308	158,777
Deferred tax liabilities	3,206	2,404
Total non-current liabilities	162,269	161,181
Total liabilities	444,344	408,949
Net assets		
Shareholder's equity		
Share capital	1,133,314	1,170,379
Capital surplus	8,247,266	8,284,331
Retained earnings (deficit)	(2,769,747)	(3,248,443)
Total shareholders' equity	6,610,833	6,206,267
Share acquisition rights	12,416	10,945
Total net assets	6,623,249	6,217,212
Total liabilities and net assets	7,067,594	6,626,161

(2) Quarterly Statements of Income
(For the three months ended January 31)

(Thousands of yen)

	FY2025 (From November 1, 2024 to January 31, 2025)
Net sales	-
Cost of sales	-
Gross profit	-
Selling, general and administrative expenses	485,358
Operating income (loss)	(485,358)
Non-operating income	
Foreign exchange gains	6,995
Other	179
Total non-operating income	7,174
Non-operating expenses	
Interest expenses	61
Total non-operating expenses	61
Ordinary income (loss)	(478,245)
Net income (loss) before income taxes	(478,245)
Income taxes: current	1,252
Income taxes: adjustment	(801)
Total income taxes	450
Total net income (loss)	(478,696)

(3) Notes to the Quarterly Financial Statements

(Notes on the segment information)

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

(Notes in the event of significant changes in shareholders' equity)

The Company's share capital and capital surplus increased by 37,064 thousand yen each due to the execution of stock option rights. As a result, the Company's share capital and capital surplus amounted to 1,170,379 thousand yen and 8,284,331 thousand yen, respectively, at the end of the first quarter of the current fiscal year.

(Notes on going concern assumptions)

Not applicable.

(Notes on the statement of quarterly cash flows)

The quarterly cashflow statements for the three months ended January 31, 2025 were not prepared. Depreciation and amortization (including amortization for intangible assets) for the three months ended January 31, 2025 are as below:

	(Thousands of yen)
	FY2025
	(From November 1, 2024 to January 31, 2025)
Depreciation and amortization	10,026

(Notes on the significant subsequent events)

Milestone achievement.

On February 4, 2025, the Company achieved a development milestone designated under an exclusive worldwide collaboration and license agreement with Novo Nordisk A/S, and as a result, the Company will receive 1,553,500 thousand yen.