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November 1, 2023

**Consolidated Financial Results
for the First Six Months of the Fiscal Year Ending March 31, 2024
(Under Japanese GAAP)**

Listed Company: Zeria Pharmaceutical Co., Ltd.

(Stock Exchange: Tokyo Stock Exchange)

Code Number: 4559

(URL: <https://www.zeria.co.jp/>)

Representative: Mitsuhiro Ibe, Representative Director, President & COO

Person in charge of reference: Tomoyuki Nishizawa, Director, Public Relations Division

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Scheduled date to submit the Quarterly Securities Report: November 6, 2023

Scheduled date to commence dividend payments: December 1, 2023

Preparation of supplementary documents to the quarterly financial results: Yes

Holding of quarterly financial results presentation: Yes (for analysts, institutional investors and the press)

(Amounts under a million yen are truncated.)

1. Consolidated Financial Highlights (April 1, 2023 through September 30, 2023)

(1) Consolidated Financial Results (cumulative)

(Percentage figures indicate changes from the same period of the previous year.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Six months ended								
September 30, 2023	36,678	8.8	5,327	(9.6)	5,495	6.1	5,396	35.0
September 30, 2022	33,712	17.9	5,894	120.6	5,182	66.3	3,998	89.0

Note: Comprehensive income: For the six months ended September 30, 2023: 11,254 million yen [39.5%]

For the six months ended September 30, 2022: 8,069 million yen [267.7%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
September 30, 2023	122.43	–
September 30, 2022	90.41	–

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	Million yen	Million yen	%	Yen
September 30, 2023	148,158	75,962	51.1	1,717.40
March 31, 2023	135,034	65,680	48.5	1,484.79

Reference: Equity: As of September 30, 2023: 75,703 million yen

As of March 31, 2023: 65,449 million yen

2. Dividends

	Annual dividends				
	First quarter	Second quarter	Third quarter	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Year ended March 31, 2023	–	18.00	–	22.00	40.00
Year ending March 31, 2024	–	22.00			
Year ending March 31, 2024 (Forecast)			–	22.00	44.00

Note: Revision of the forecast of dividends most recently announced: None

3. Consolidated Financial Forecast for Fiscal Year Ending March 31, 2024 (April 1, 2023 through March 31, 2024)

(Percentage figures indicate changes from the same period of the previous year.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	73,000	6.8	9,100	0.9	9,000	18.7	7,000	13.0	158.80

Note: Revision of the financial forecast most recently announced: None

* Notes

(1) Changes in significant subsidiaries during the six months ended September 30, 2023 (changes in specified subsidiaries resulting in changes in scope of consolidation): None

Inclusion: – (Company name: –) Exclusion: – (Company name: –)

(2) Application of special accounting for preparing the quarterly consolidated financial statements: Yes

Note: For details, please refer to “2. Quarterly Consolidated Financial Statements and Significant Notes Thereto, (4) Notes to quarterly consolidated financial statements” on page 10 of the Attached Material.

(3) Changes in accounting policies, changes in accounting estimates, and restatement of prior period financial statements after error corrections

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

2) Changes in accounting policies due to other reasons: None

3) Changes in accounting estimates: None

4) Restatement of prior period financial statements after error corrections: None

(4) Number of shares issued (common shares)

1) Number of shares issued as of the end of the term (including treasury shares):

As of September 30, 2023: 53,119,190 shares As of March 31, 2023: 53,119,190 shares

2) Number of shares of treasury shares as of the end of the term:

As of September 30, 2023: 9,039,119 shares As of March 31, 2023: 9,038,982 shares

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

For the six months ended September 30, 2023: 44,080,153 shares

For the six months ended September 30, 2022: 44,229,546 shares

* Quarterly Results Reports Are Exempt from Quarterly Review Conducted by Certified Public Accountants or An Audit Corporation

* Cautionary Statement with Respect to Appropriate Use of Financial Forecast and Other Special Matters

The description about the future including the projection in this document is based on information available to the Company at present and certain presumptions which the Company considers reasonable. Consequently, any descriptions herein do not constitute assurances regarding actual results by the Company. The actual results for future terms may differ from the information in this document due to various factors. For the assumptions made in financial forecasts and cautions concerning the use thereof, please refer to “1. Qualitative Information on Quarterly Financial Results, (3) Explanation of consolidated financial forecasts and other forward-looking statements” on page 4 of the Attached Material.

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1. Qualitative Information on Quarterly Financial Results

(1) Explanation of operating results

Net sales for the first six months of the fiscal year ending March 31, 2024 were 36,678 million yen (up 8.8% from the same period of the previous fiscal year). At the same time, operating profit was 5,327 million yen (down 9.6% from the same period of the previous fiscal year) due to the increase in expenditures resulting from a partial revision of the pharmaceutical price regulation scheme in the UK in addition to increases mainly in promotion expenses and depreciation. Ordinary profit was 5,495 million yen (up 6.1% from the same period of the previous fiscal year) as a result of recording a small amount of foreign exchange gains for the period under review despite recording a large amount of foreign exchange losses from the sudden appreciation of the Swiss franc during the previous period. Profit attributable to owners of parent was 5,396 million yen (up 35.0% from the same period of the previous fiscal year) as a result of recording reversal of provision for loss on cancellation of contracts as extraordinary income.

Following are the results by business segment.

(i) *Ethical Pharmaceuticals Business*

As for our mainstay product, Asacol, a therapeutic agent for ulcerative colitis, sales in the domestic market faced challenging circumstances, owing in part to the impact of the NHI drug price revision implemented in April of 2023. Despite this, sales were steady overall as a result of strong performance in regions such as the UK and Germany due to growth in sales of Asacol 1600 mg in overseas markets. Sales of DIFICLIR, a therapeutic agent for Clostridium difficile infections, achieved a significant sales growth as a result of continuous aggressive investment of sales resources in overseas markets, which lead to a significant increase in sales in France, the UK, and Spain. In April 2023, we were transferred approval from Astellas Pharma Inc. for the manufacturing and marketing of the drug in Japan and worked to promote the product (domestic sales name: Dafclir). However, sales of Entocort (domestic sales name: Zentacort), an inflammatory bowel disease (IBD) therapeutic agent, struggled after the launch of generic drugs in certain countries outside Japan. With regard to Ferinject, we are working to build the market, particularly in the obstetrics and gynecology and gastroenterology fields.

As a result, net sales in the business amounted to 23,900 million yen (up 11.1% from the same period of the previous fiscal year).

(ii) *Consumer Healthcare Business*

As for the Hepalyse range, our mainstay product, due to the relaxing of behavioral restrictions related to the COVID-19 pandemic and recovery in the flow of people, sales of both the pharmaceutical Hepalyse range and the Hepalyse W range for convenience stores increased. Sales of the Chondroitin range also remained strong, due in part to aggressive advertising and promotional investments. In addition, sales increased for both the European herbal preparation range, including Prefemin, a treatment for premenstrual syndrome (PMS), which transferred to a Type-2 OTC drug in April 2023, and the Masdent range of medicated toothpaste for preventing periodontal disease and bad breath.

As a result, net sales in the business amounted to 12,700 million yen (up 4.7% from the same period of the previous fiscal year).

(iii) *Other*

Net sales in this segment amounted to 77 million yen (up 1.9% from the same period of the previous fiscal year), mainly due to insurance agency business and real estate lease revenue.

(2) Explanation of financial position

(i) *Assets, liabilities, and net assets*

Total assets at the end of the second quarter of the fiscal year ending March 31, 2024 were 148,158 million yen, an increase of 13,124 million yen from the end of the previous fiscal year. Current assets increased 7,752 million yen to 55,956 million yen from the end of the previous fiscal year, and non-current assets increased 5,371 million yen to 92,202 million yen from the end of the previous fiscal year. Major changes in current assets included an increase of 2,248 million yen in cash and deposits, an increase of 4,146 million yen in notes and accounts receivable - trade, and an increase of 1,520 million yen in inventories such as merchandise and finished goods. The changes in non-current assets were an increase of 990 million yen in property, plant and equipment, an increase of 2,725 million yen in intangible assets, and an increase of 1,655 million yen in investments and other assets.

Total liabilities at the end of the quarter under review were 72,196 million yen, an increase of 2,842 million yen from the end of the previous fiscal year. Current liabilities increased 5,863 million yen to 53,021 million yen from the end of the previous fiscal year, and non-current liabilities decreased 3,020 million yen to 19,174 million yen from the end of the previous fiscal year. Main changes in current liabilities were an increase of 1,067 million yen in accounts payable - trade, an increase of 3,648 million yen in short-term borrowings and an increase of 982 million yen in income taxes payable. Main changes in non-current liabilities were a decrease of 2,523 million yen in long-term borrowings and a decrease of 897 million yen in provision for loss on cancellation of contracts.

Net assets at the end of the quarter under review were 75,962 million yen, an increase of 10,281 million yen from the end of the previous fiscal year. This was mainly due to profit attributable to owners of parent of 5,396 million yen, payment of 969 million yen as dividends declared at the end of the previous period, and an increase of 4,824 million yen in foreign currency translation adjustment.

As a result, equity ratio at the end of the quarter under review increased by 2.6% from the end of the previous fiscal year to 51.1%.

(ii) *Status of cash flows*

Cash and cash equivalents (below, "cash") at the end of the quarter under review increased 2,248 million yen from the beginning of the period to 18,343 million yen. This was mainly due to net cash provided by operating activities of 4,964 million yen, despite net cash used in investing activities of 2,186 million yen and net cash used in financing activities of 2,285 million yen.

The status of each cash flow and its factors for the first six months of the current fiscal year are as follows.

[Net cash provided by (used in) operating activities]

Net cash provided by operating activities amounted to 4,964 million yen in the first six months of the current fiscal year (down 367 million yen from the same period of the previous fiscal year). This was due to factors including profit before income taxes of 6,412 million yen, depreciation of 3,031 million yen, a decrease in provision for loss on cancellation of contracts of 923 million yen, an increase in trade receivables of 2,804 million yen, an increase in inventories of 824 million yen, and an increase in trade payables of 1,034 million yen.

[Net cash provided by (used in) investing activities]

Net cash used in financing activities totaled 2,186 million yen in the first six months of the current fiscal year (down 1,223 million yen from the same period of the previous fiscal year). This was mainly due to expenditures of 1,395 million yen for the purchase of property, plant and equipment and 888 million yen for the purchase of intangible assets.

[Net cash provided by (used in) financing activities]

Net cash used in financing activities totaled 2,285 million yen in the first six months of the current fiscal year (down 166 million yen from the same period of the previous fiscal year). This was mainly due to an increase of 1,168 million yen in short-term borrowings, proceeds from long-term borrowings of 500 million yen, repayments of long-term borrowings of 2,824 million yen, and dividends paid of 966 million yen.

(3) Explanation of consolidated financial forecasts and other forward-looking statements

The full-year consolidated financial forecasts for the fiscal year ending March 31, 2024 are expected to mainly be in line with expectations, primarily in the overseas Ethical Pharmaceuticals Business, and we are leaving the full-year figures announced on May 11, 2023 unchanged due to uncertainties about the impact of soaring raw material and energy prices and exchange rate trends. If it becomes necessary to revise the financial forecast, we will disclose the revised forecast promptly.

2. Quarterly Consolidated Financial Statements and Significant Notes Thereto

(1) Quarterly consolidated balance sheet

(Thousands of yen)

	As of March 31, 2023	As of September 30, 2023
Assets		
Current assets		
Cash and deposits	16,219,078	18,468,022
Notes and accounts receivable - trade	17,512,925	21,659,778
Merchandise and finished goods	6,843,723	8,018,926
Work in process	1,433,308	1,373,181
Raw materials and supplies	4,487,158	4,892,884
Other	1,800,930	1,635,979
Allowance for doubtful accounts	(93,366)	(92,496)
Total current assets	48,203,757	55,956,275
Non-current assets		
Property, plant and equipment		
Buildings, net	6,772,573	6,662,008
Land	12,359,997	12,474,232
Other, net	5,458,805	6,445,597
Total property, plant and equipment	24,591,375	25,581,838
Intangible assets		
Goodwill	5,299,798	5,133,326
Sales right	28,157,670	30,191,579
Other	8,473,201	9,331,334
Total intangible assets	41,930,669	44,656,240
Investments and other assets		
Investment securities	6,849,304	8,535,278
Retirement benefit asset	12,927,173	12,918,910
Other	578,716	551,177
Allowance for doubtful accounts	(46,460)	(40,874)
Total investments and other assets	20,308,733	21,964,492
Total non-current assets	86,830,779	92,202,571
Total assets	135,034,536	148,158,847
Liabilities		
Current liabilities		
Accounts payable - trade	1,996,122	3,063,342
Short-term borrowings	34,890,470	38,539,273
Income taxes payable	749,106	1,731,739
Provision for bonuses	1,554,662	1,043,674
Other	7,967,956	8,643,360
Total current liabilities	47,158,318	53,021,390
Non-current liabilities		
Long-term borrowings	14,541,480	12,018,050
Provision for loss on cancellation of contracts	897,300	-
Retirement benefit liability	234,465	216,826
Asset retirement obligations	56,031	56,135
Other	6,466,230	6,883,966
Total non-current liabilities	22,195,507	19,174,978
Total liabilities	69,353,826	72,196,369

(Thousands of yen)

	As of March 31, 2023	As of September 30, 2023
Net assets		
Shareholders' equity		
Share capital	6,593,398	6,593,398
Capital surplus	11,685,121	11,685,121
Retained earnings	53,462,589	57,889,601
Treasury shares	(18,264,989)	(18,265,312)
Total shareholders' equity	53,476,120	57,902,808
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(314,469)	949,991
Foreign currency translation adjustment	8,015,623	12,840,432
Remeasurements of defined benefit plans	4,272,642	4,009,909
Total accumulated other comprehensive income	11,973,796	17,800,333
Non-controlling interests	230,793	259,335
Total net assets	65,680,710	75,962,478
Total liabilities and net assets	135,034,536	148,158,847

(2) Quarterly consolidated statement of income and quarterly consolidated statement of comprehensive income

Quarterly consolidated statement of income

(Thousands of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Net sales	33,712,480	36,678,404
Cost of sales	9,376,722	9,631,957
Gross profit	24,335,758	27,046,446
Selling, general and administrative expenses	18,441,079	21,719,007
Operating profit	5,894,678	5,327,439
Non-operating income		
Interest income	26,461	46,176
Dividend income	158,136	192,672
Foreign exchange gains	–	1,017
Recoveries of written off receivables	–	89,761
Other	45,555	77,461
Total non-operating income	230,153	407,090
Non-operating expenses		
Interest expenses	181,259	226,110
Foreign exchange losses	748,121	–
Other	13,205	12,481
Total non-operating expenses	942,586	238,591
Ordinary profit	5,182,245	5,495,938
Extraordinary income		
Gain on sale of non-current assets	260	–
Gain on sale of investment securities	19,940	0
Reversal of provision for loss on cancellation of contracts	–	923,331
Total extraordinary income	20,200	923,332
Extraordinary losses		
Loss on retirement of non-current assets	3,350	6,336
Provision for loss on cancellation of contracts	228,300	–
Total extraordinary losses	231,651	6,336
Profit before income taxes	4,970,794	6,412,933
Income taxes	964,014	1,005,062
Profit	4,006,779	5,407,870
Profit attributable to non-controlling interests	8,199	11,093
Profit attributable to owners of parent	3,998,580	5,396,776

Quarterly consolidated statement of comprehensive income

(Thousands of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Profit	4,006,779	5,407,870
Other comprehensive income		
Valuation difference on available-for-sale securities	(264,896)	1,264,461
Foreign currency translation adjustment	4,476,703	4,844,478
Remeasurements of defined benefit plans, net of tax	(148,940)	(262,732)
Total other comprehensive income	4,062,866	5,846,207
Comprehensive income	8,069,646	11,254,078
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	8,023,106	11,223,314
Comprehensive income attributable to non-controlling interests	46,539	30,764

(3) Quarterly consolidated statement of cash flows

(Thousands of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Cash flows from operating activities		
Profit before income taxes	4,970,794	6,412,933
Depreciation	2,466,358	3,031,173
Amortization of goodwill	354,879	363,836
Increase (decrease) in provision for bonuses	(514,895)	(562,105)
Increase (decrease) in provision for loss on cancellation of contracts	228,300	(923,331)
Increase (decrease) in retirement benefit liability	109,324	(17,638)
Interest and dividend income	(184,597)	(238,849)
Interest expenses	181,259	226,110
Decrease (increase) in trade receivables	(1,289,682)	(2,804,465)
Decrease (increase) in inventories	(409,623)	(824,917)
Increase (decrease) in trade payables	193,809	1,034,301
Decrease (increase) in other current assets	(164,194)	(74,785)
Increase (decrease) in other current liabilities	215,451	549,034
Decrease (increase) in retirement benefit asset	(354,809)	(493,330)
Other, net	(117,947)	(286,874)
Subtotal	5,684,428	5,391,092
Interest and dividends received	184,616	238,593
Interest paid	(180,360)	(216,497)
Income taxes paid	(356,493)	(448,416)
Net cash provided by (used in) operating activities	5,332,190	4,964,771
Cash flows from investing activities		
Purchase of property, plant and equipment	(908,651)	(1,395,136)
Purchase of intangible assets	(156,032)	(888,433)
Purchase of investment securities	(132,488)	(2,313)
Proceeds from sale of investment securities	215,908	1
Other, net	17,787	99,315
Net cash provided by (used in) investing activities	(963,476)	(2,186,567)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	1,873,266	1,168,875
Proceeds from long-term borrowings	500,000	500,000
Repayments of long-term borrowings	(3,028,710)	(2,824,420)
Repayments of lease liabilities	(123,158)	(160,870)
Purchase of treasury shares	(538,398)	(323)
Dividends paid	(798,347)	(966,355)
Dividends paid to non-controlling interests	(3,929)	(2,308)
Net cash provided by (used in) financing activities	(2,119,276)	(2,285,403)
Effect of exchange rate change on cash and cash equivalents	1,340,254	1,756,142
Net increase (decrease) in cash and cash equivalents	3,589,691	2,248,943
Cash and cash equivalents at beginning of period	11,579,282	16,094,078
Cash and cash equivalents at end of period	15,168,974	18,343,022

(4) Notes to quarterly consolidated financial statements

(Notes on premise of a going concern)

Not applicable.

(Notes on significant changes in the amount of shareholders' equity)

Not applicable.

(Adoption of special accounting methods for preparation of quarterly consolidated financial statements)

Calculation of tax expenses

Tax expenses were calculated by reasonably estimating the effective tax rate after applying tax effect accounting to the profit before income taxes for the fiscal year that includes the second quarter of the current fiscal year and multiplying profit before income taxes by such estimated effective tax rate.

(Segment information, etc.)

[Segment information]

I First six months of the previous fiscal year (from April 1, 2022 to September 30, 2022)

1. Information on net sales and profit or loss by reportable segment

(Thousands of yen)

	Reportable segment			Other (Note 1)	Total	Adjustment (Note 2)	Amount recorded in quarterly consolidated statement of income (Note 3)
	Ethical Pharmaceuticals Business	Consumer Healthcare Business	Total				
Net sales							
Sales to external customers	21,505,406	12,131,357	33,636,763	75,716	33,712,480	–	33,712,480
Intersegment sales and transfers	2,694	58	2,753	219,681	222,434	(222,434)	–
Total	21,508,101	12,131,416	33,639,517	295,398	33,934,915	(222,434)	33,712,480
Segment profit	5,867,879	2,454,974	8,322,853	116,456	8,439,309	(2,544,631)	5,894,678

(Notes) 1. “Other” is a business segment not included in the reportable segments and includes the insurance agency business and real estate business.

2. Adjustment of segment profit of (2,544,631) thousand yen is mainly corporate expenses, such as general and administrative expenses that are not allocated to reportable segments.
3. Segment profit is adjusted with operating profit in the quarterly consolidated statement of income.

2. Information on impairment losses on non-current assets or goodwill by reportable segment
Not applicable.

II First six months of the current fiscal year (from April 1, 2023 to September 30, 2023)

1. Information on net sales and profit or loss by reportable segment

(Thousands of yen)

	Reportable segment			Other (Note 1)	Total	Adjustment (Note 2)	Amount recorded in quarterly consolidated statement of income (Note 3)
	Ethical Pharmaceuticals Business	Consumer Healthcare Business	Total				
Net sales							
Sales to external customers	23,900,997	12,700,282	36,601,280	77,124	36,678,404	–	36,678,404
Intersegment sales and transfers	2,958	62	3,020	320,078	323,099	(323,099)	–
Total	23,903,955	12,700,344	36,604,300	397,202	37,001,503	(323,099)	36,678,404
Segment profit	5,257,968	2,526,140	7,784,109	124,092	7,908,202	(2,580,762)	5,327,439

(Notes) 1. “Other” is a business segment not included in the reportable segments and includes the insurance agency business and real estate business.

2. Adjustment of segment profit of (2,580,762) thousand yen is mainly corporate expenses, such as general and administrative expenses that are not allocated to reportable segments.
3. Segment profit is adjusted with operating profit in the quarterly consolidated statement of income.

2. Information on impairment losses on non-current assets or goodwill by reportable segment
Not applicable.

3. Supplemental Information

(1) Sales results

The table below shows sales results by business segment in the first six months of the current fiscal year.

(Thousands of yen)

Name of segment	First six months of the current fiscal year (from April 1, 2023 to September 30, 2023)	Increase/(decrease) over the same period of the previous fiscal year (%)
Ethical Pharmaceuticals Business	23,900,997	11.1
Consumer Healthcare Business	12,700,282	4.7
Total reportable segment	36,601,280	8.8
Other	77,124	1.9
Total	36,678,404	8.8

(Note) Inter-segment transactions are offset and eliminated.

(2) Sales of major products and merchandise Consolidated

(Thousands of yen)

	First six months of the previous fiscal year (from April 1, 2022 to September 30, 2022)	First six months of the current fiscal year (from April 1, 2023 to September 30, 2023)	Percentage change (%)
1. Ethical Pharmaceuticals Business	21,505,406	23,900,997	11.1
Asacol	9,881,146	10,097,551	2.2
DIFICLIR	3,895,442	6,545,802	68.0
Entocort	2,935,555	2,447,326	(16.6)
Acofide	1,541,840	1,522,454	(1.3)
Other	3,251,421	3,287,862	1.1
2. Consumer Healthcare Business	12,131,357	12,700,282	4.7
Hepalyse range	4,698,724	5,190,313	10.5
Chondroitin range	2,634,015	2,862,851	8.7
WithOne range	620,943	612,894	(1.3)
Other	4,177,673	4,034,223	(3.4)
3. Other Business	75,716	77,124	1.9
Total	33,712,480	36,678,404	8.8

(3) Status of pipeline of new drugs

I. Domestic

As of November 1, 2023

Stage	Development Code/ Generic Name	Development	Indications	Classification	Origin
NDA filed	ZG-801/Patiromer Sorbitex Calcium	Zeria	Hyperkalemia	Potassium binder	In-licensed
Phase III	Z-338/Acotiamide	Zeria	Pediatric functional dyspepsia	Upper gastrointestinal motility modulator	Original
Phase II	ZG-802/Acotiamide	Zeria	Underactive bladder	Lower urinary tract function modulator	Original
Phase II* (Investigator-Initiated Trial)	Z-338/Acotiamide	Kyushu University	Esophagogastric junction outflow obstruction	Upper gastrointestinal motility modulator	Original

*: Supported by a grant from Japan Agency for Medical Research and Development (AMED)

II. Overseas

Stage	Development Code/ Generic Name	Development	Indications	Classification	Origin
Phase III (Europe)	Z-338/Acotiamide	Zeria	Functional dyspepsia	Upper gastrointestinal motility modulator	Original
NDA approved (Honduras, Dominican Republic, Ecuador, Chile, El Salvador, Peru)	Z-338/Acotiamide	Faes Farma	Functional dyspepsia	Upper gastrointestinal motility modulator	Original (Out-licensed)
NDA approved (Thailand)	Z-338/Acotiamide	Meiji Seika Pharma	Functional dyspepsia	Upper gastrointestinal motility modulator	Original (Out-licensed)
NDA filed (Vietnam)	Z-338/Acotiamide	Pharmaceutical Joint Stock Company of February 3rd	Functional dyspepsia	Upper gastrointestinal motility modulator	Original
NDA filed (Colombia, Costa Rica, Guatemala, Panama, Nicaragua)	Z-338/Acotiamide	Faes Farma	Functional dyspepsia	Upper gastrointestinal motility modulator	Original (Out-licensed)

Launched in Overseas

Launch Date	Development Code/ Generic Name	Development	Indications	Classification	Origin
October 2023 (Mexico)	Z-338/Acotiamide	Faes Farma	Functional dyspepsia	Upper gastrointestinal motility modulator	Original (Out-licensed)