Financial Results for the Six Months ended September 30, 2024
[Japanese GAAP] (non-consolidated)

November 8, 2024

BrightPath Biotherapeutics Co., Ltd. Listed Market Growth, TSE
TSE Code 4594 URL https://www.brightpathbio.com/english/
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Scheduled date to file semi-annual securities report : November 8, 2024
Scheduled date of dividend payment commencement : —
Supplementary materials for financial statements : None
Briefing of financial results : Yes (for analysts/institutional investors)

(Millions of yen, rounded down to the nearest million)

1. Financial results for the six months ended September 30, 2024 (April 1, 2024 – September 30, 2024)

(1) Results of Operation (Percentages represent changes from the same period of previous year)

	Net sales		Operating income		Ordinary income		Net income	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2024	0	25.0	-542	—	-537	—	-538	—
September 30, 2023	0	-75.0	-550	—	-551	—	-553	—

	Net income per share	Fully diluted net income per share
Six months ended	Yen	Yen
September 30, 2024	-7.11	—
September 30, 2023	-8.81	—

(Note) 1. Fully diluted net income per share is not stated as net loss was recorded for this period although there are residual shares.

(2) Financial Position

	Total assets	Net assets	Equity ratio
As of	Million yen	Million yen	%
September 30, 2024	1,696	1,234	71.4
March 31, 2024	1,230	978	77.7

(Reference) Shareholders' equity As of September 30, 2024 1,211 million yen
As of March 31, 2024 956 million yen

2. Dividends

	Annual dividends per share				
	1Q	2Q	3Q	4Q	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended March 31, 2024	—	0.00	—	0.00	0.00
Fiscal year ending March 31, 2025	—	0.00			
Fiscal year ending March 31, 2025 (Forecast)			—	0.00	0.00

(Note) 1. There is no change in dividends information from the latest official forecast.

3. Projected financial results for the fiscal year ending March 31, 2025 (April 1, 2024 – March 31, 2025)

(Percentages represent changes from the same period of previous year)

	Net sales		Operating income		Ordinary income		Net income		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	0	-31.3	-925	—	-925	—	-927	—	-13.08

(Note) 1. The Company manages business results on an annual basis, and therefore only the full-year financial forecasts are disclosed.
2. There is no change in projected financial results from the latest official forecast.

[Notes]

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

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

1) Changes in accounting policies due to revisions of accounting standards, etc.	: None
2) Changes in accounting policies due to other reasons than above 1)	: None
3) Changes in accounting estimates	: None
4) Restatements	: None

(3) Number of shares outstanding (common stock)

1) Number of shares outstanding at the end of the period (including treasury stock)	As of September 30, 2024	83,791,300 shares	As of March 31, 2024	70,741,300 shares
2) Number of shares of treasury stock at the end of the period	As of September 30, 2024	1 share	As of March 31, 2024	1 share
3) Average number of shares during the period	6 months ended September 30, 2024	75,817,309 shares	6 months ended September 30, 2023	62,891,199 shares

* Review of the Japanese-language original of the attached semi-annual non-consolidated financial statements by certified public accountants or an audit firm: None
* Explanations regarding appropriate use of forecasts and projections of financial results, and other specific notes
  - All forecasts and projections contained in this document are based on the information available and certain assumptions deemed reasonable by the Company at this time. They are not intended to represent our promise to attain them as a goal. Actual results may differ substantially due to various reasons. For details on the assumptions and conditions for forecasts and projections as well as notes on their use, please refer to “1. Overview of Business Results, etc. (4) Outlook for the Fiscal Year Ending March 31, 2025” on page 5 of the attachment.

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1. Overview of Business Results, etc.

(1) Overview of Operating Results for the Six Months Ended September 30, 2024

BrightPath Biotherapeutics Co., Ltd. (the "Company") has built an environment for exploring and developing cancer immunotherapeutics (drugs that treat cancer by utilizing the immune system) during the six months ended September 30, 2024.

Cell therapy agents

<iPSC derived natural killer T-cell (NKT cell) therapy: BP2201>

BP2201 (iPS-NKT) is a candidate agent for novel allogeneic cell therapy. This novel therapy uses natural killer T-cells (NKT cells)[1] manufactured in large quantities through iPS cell technology to treat cancer, since NKT cells have multifaceted anti-tumor effects including cancer-killing capabilities.

The Company has obtained an exclusive license to use the patent for iPSC derived NKT cells (iPS-NKT) from Institute of Physical and Chemical Research, a.k.a. RIKEN. This patent, registered in Japan, the US and the EU, extensively and exclusively protects the use of iPS-NKT for CAR-T cell therapy and other kinds of allogeneic cell therapy. This license has allowed the Company to establish the manufacturing process capable of differentiating iPS cells in the master iPS cell bank into high-purity and high-yield NKT cells and facilitated the Company's introduction of gene-editing technologies. At Chiba University where clinical research for autologous NKT cell therapy has been continued since the beginning of the 2000s, an investigator-initiated Phase 1 trial of iPS-NKT in patients with head and neck cancers started in June 2020 and finished in January 2024. This was the world's first clinical application of iPS-NKT in cellular immunotherapy. This clinical trial demonstrated acceptable tolerability and safety as the primary endpoints and confirmed preliminary anti-tumor activity, as shown by the topline data published at an academic conference in February 2024.

Non-genetically edited iPS-NKT cells used in this clinical trial can serve as a cornerstone or platform for developing novel iPS-NKT cells by transducing CAR-T cells targeting various tumor antigens. Such platform will facilitate the application of iPS-NKT cells to treatment of various types of cancer in many regions of the world.

<CAR-iPSNKT cell therapy: BP2202>

BP2202 (CAR-iPSNKT) is a new CAR-T cell therapy[2] using unmodified iPS-NKT cells with chimeric antigen receptors (CAR) that can recognize cancer antigens with the aim of enhancing tumor killing capabilities.

Compared to non-genetically edited iPS-NKT cells, HER2 CAR iPS-NKT experimentally manufactured by the Company exhibits enhanced anti-tumor effects in mice tests.

In May 2023, the Company obtained a license for the STAR-CRISPR™ gene editing technology. This license enables the Company to create programs for advanced gene-edited CAR-iPS NKT cell therapy to treat various types of cancer including solid tumors. The Company's development project to create BP2202 as prototype CAR-NKT cells for hematologic cancer is underway. In parallel, the Company is preparing the creation of the master cell bank and GMP-compliant manufacturing.

<HER2 CAR-T cell therapy: BP2301>

BP2301 is a chimeric antigen receptor gene-transfected T-cell (CAR-T cell) therapy which targets HER2 that is highly expressed in various solid tumors. Until today, CAR-T cell therapies have been approved globally with excellent clinical benefits demonstrated in clinical trials for hematologic cancers. However, the deployment of CAR-T cell therapies to treat solid tumors, from which a larger number of people suffer, faces a challenge due to the lack of sufficient clinical efficacy of CAR-T cells resulting from their exhaustion and dysfunction in the immune-suppressive tumor microenvironment.

The Company has successfully overcome this challenge by developing a technology using CAR-T cells rich in stem cell memory phenotypes. Owing to the high replicability and long-term viability of such CAR-T cells in the patient's body, BP2301 is a promising solution to enhance resistance to T-cell exhaustion and to achieve long-lasting anti-tumor effects in the tumor microenvironment. This success is attributed to the joint development of a novel cell culture method with Professor Yozo Nakazawa and Professor Shigeki Yagyu of Shinshu University, based on Professor Nakazawa's non-viral gene transfer method.

In the Phase 1 investigator-initiated clinical trial started in May 2022 at Shinshu University, the treatment of HER2-positive relapsed or advanced sarcomas and gynecological malignancies is being tested.

Antibody drugs

Since immune checkpoint molecules[3] or immunomodulatory molecules suppress the immune system to eliminate tumor cells, the Company is developing antibody drugs capable of binding to such molecules and inhibiting their function. The Company's antibody drug development pipelines cover BP1200, BP1202, BP1210 and BP1212. BP1200 and BP1202 target CD73 and CD39 respectively, both of which help prevent the production of immunosuppressive adenosine. BP1210 targets TIM-3, which is expressed in immune cells and restraints anti-tumor immunity. Furthermore, BP1212 is a CD39/TIM-3 bispecific antibody targeting immune cells which co-express CD39 and TIM-3 and simultaneously blocking multiple immunosuppressive mechanisms. The effort to obtain further non-clinical data for antibody profiling is underway during the course of licensing activities.

In the process, the Company has created BP1223, a CD39/CD3 bispecific antibody, stimulating T-cells to reach tumor cells. The Company will start joint research with National Cancer Center Hospital East for non-clinical studies to confirm pharmaceutical benefits, pharmacological effects and mode-of-action analysis targeting blood cancer including acute myeloid leukemia. The research of BP1223 up to now is to be presented at the 66th American Society of Hematology Annual Meeting and Exposition in December, 2024.

Cancer vaccines

<Fully-personalized neoantigen vaccine with immune checkpoint antibodies: BP1209>

BP1209 is a new platform of fully-personalized neoantigen vaccines[4] optimized to induce each individual patient's anti-tumor immunity targeting immunogenic neoantigens derived from mutations in cancer cell derived genes. BP1209 uses checkpoint inhibitor antibodies to deliver neoantigen peptides to dendritic cells acting as messengers to T-cells. To facilitate the binding of BP1209 to such antibodies, the Company's original linker technology is utilized. The Company has demonstrated in a tumor-bearing mouse model that efficient delivery of vaccine antigens to dendritic cells which direct anti-tumor immunity can induce many more cancer-killing T-cells which identify and attack neoantigens than peptides alone do.

As a consequence of all of the foregoing, the Company recorded the financial results for the six months ended September 30, 2024 as follows : operating loss of 542,559 thousand yen (550,569 thousand yen in the corresponding period of the prior year), ordinary loss of 537,786 thousand yen (551,566 thousand yen in the corresponding period of the prior year), and net loss of 538,736 thousand yen (553,922 thousand yen in the corresponding period of the prior year).

<Glossary>

1. NKT cell

An immune cell combining the properties of natural killer (NK) cells and T-cells and serving as a functional bridge between innate and acquired immunity. NKT cells have the ability to directly kill cancer

cells through T-cell receptors or NK cell receptors and at the same time have an adjuvant action that activates other immune cells such as T-cells and dendritic cells. When activated, NKT cells produce a variety of cytokines and promote the activation of NK cells belonging to the innate immune system and the maturation of dendritic cells. Mature dendritic cells further proliferate and activate killer T-cells belonging to the acquired immune system, thereby synergistically enhancing anti-tumor effects.

2. CAR-T cell therapy

Chimeric antigen receptor T-cell therapy. Chimeric antigen receptors that recognize antigens expressed by cancer cells are gene-transfected into T-cells (a type of lymphocyte with anti-tumor immunity), which are then grown in culture and administered.

3. Immune checkpoint molecule

A group of molecules that suppress the immune response to self as well as suppress excessive immune responses in order to maintain immune homeostasis. In cancer immunity, they are present to prevent the attack on self by over-activation, but in the carcinogenic process, they are used by cancer cells to evade attack from the immune system and to proliferate.

4. Fully personalize neoantigen vaccine

A tailor-made cancer vaccine that searches for neoantigens in cancer cells of individual patients. Clinical trials currently conducted overseas by academia and leading development companies include those for mRNA vaccines, that is, lipid nanoparticles (LNP) loaded with mRNAs coding for neoantigens.

(2) Overview of Financial Position for the Six Months Ended September 30, 2024

(i) Assets

As of September 30, 2024, total assets were 1,696,224 thousand yen, an increase of 465,967 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 482,034 thousand yen in cash and deposits due to issuance of shares and straight bonds.

(ii) Liabilities

As of September 30, 2024, total liabilities were 462,117 thousand yen, an increase of 210,847 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 212,500 thousand yen in current portion of bonds payable.

(iii) Net assets

As of September 30, 2024, net assets were 1,234,107 thousand yen, an increase of 255,120 thousand yen from the end of the prior fiscal year. The main factors for this include an increase of 794,520 thousand yen in total in capital stock and capital surplus due to issuance of new shares, and a decrease of a net loss of 538,736 thousand yen. As a result of the above, equity ratio was 71.4% compared to 77.7% at the end of the prior fiscal year.

(3) Overview of Cash Flows for the Six Months Ended September 30, 2024

As of September 30, 2024, cash and cash equivalents (hereinafter “net cash”) amounted to 1,539,394 thousand yen, an increase of 482,034 thousand yen from the end of the prior fiscal year. The situation of each cash flow for the six months ended September 30, 2024 and the underlying factors are as follows:

(i) Cash flows from operating activities

Net cash used in operating activities amounted to 520,584 thousand yen (466,327 thousand yen used in the corresponding period of the prior year). This was mainly due to recording loss before income taxes of 537,786 thousand yen.

(ii) Cash flows from investing activities

No cash flows were recorded in investing activities (1,454 thousand yen used in the corresponding period of the prior year).

(iii) Cash flows from financing activities

Net cash used in financing activities amounted to 1,002,619 thousand yen (none recorded in the corresponding period of the prior year). This was mainly due to 788,581 thousand yen of proceeds from issuance of shares resulting from exercise of share acquisition rights.

(4) Outlook for the Fiscal Year Ending March 31, 2025

Our recent business outlook is the same as the projected financial results announced on May 10, 2024.

3. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of March 31, 2024	As of September 30, 2024
Assets		
Current assets		
Cash and deposits	1,057,360	1,539,394
Accounts receivable - trade	6	30
Other	123,594	107,502
Total current assets	1,180,960	1,646,927
Non-current assets		
Property, plant and equipment	0	0
Intangible assets	0	0
Investments and other assets	49,296	49,296
Total non-current assets	49,296	49,296
Total assets	1,230,257	1,696,224
Liabilities		
Current liabilities		
Accounts payable - trade	20	15
Current portion of bonds payable	112,500	325,000
Income taxes payable	12,815	12,436
Other	65,675	60,302
Total current liabilities	191,011	397,755
Non-current liabilities		
Provision for retirement benefits	37,610	41,667
Asset retirement obligations	22,648	22,694
Other	0	0
Total non-current liabilities	60,258	64,361
Total liabilities	251,270	462,117
Net assets		
Shareholders' equity		
Capital stock	650,661	1,047,921
Capital surplus	2,959,195	3,356,455
Retained earnings	-2,653,715	-3,192,452
Treasury stock	-0	-0
Total shareholders' equity	956,141	1,211,925
Share acquisition rights	22,845	22,182
Total net assets	978,987	1,234,107
Total liabilities and net assets	1,230,257	1,696,224

(2) Statements of Operations

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Net sales	44	56
Cost of sales	11	14
Gross profit	33	42
Selling, general and administrative expenses	550,603	542,601
Operating income	-550,569	-542,559
Non-operating income		
Interest income	6	47
Foreign exchange gains	—	2,098
Settlement income	—	5,939
Other	186	4
Total non-operating income	193	8,089
Non-operating expenses		
Foreign exchange losses	1,190	—
Share issuance cost	—	3,226
Other	—	90
Total non-operating expenses	1,190	3,316
Ordinary income	-551,566	-537,786
Extraordinary losses		
Impairment loss	1,406	—
Total extraordinary losses	1,406	—
Income before income taxes	-552,972	-537,786
Income taxes - current	950	950
Total income taxes	950	950
Net income	-553,922	-538,736

(3) Statements of Cash Flows

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Cash flows from operating activities		
Loss before income taxes	-552,972	-537,786
Depreciation	48	—
Impairment loss	1,406	—
Interest and dividend income	-6	-47
Decrease (increase) in notes and accounts receivable - trade	24	-24
Increase (decrease) in notes and accounts payable - trade	-64	-4
Increase (decrease) in retirement benefit liability	660	4,057
Other, net	86,468	9,140
Subtotal	-464,436	-524,665
Interest and dividend income received	9	42
Income taxes paid	-1,900	-1,900
Settlement received	—	5,939
Net cash provided by (used in) operating activities	-466,327	-520,584
Cash flows from investing activities		
Purchase of intangible assets	-1,454	—
Net cash provided by (used in) investing activities	-1,454	—
Cash flows from financing activities		
Proceeds from issuance of bonds	—	500,000
Redemption of bonds	—	-287,500
Payments for purchase of treasury share acquisition rights	—	-1,042
Proceeds from issuance of share acquisition rights	—	2,580
Proceeds from issuance of shares resulting from exercise of share acquisition rights	—	788,581
Net cash provided by (used in) financing activities	—	1,002,619
Net increase (decrease) in cash and cash equivalents	-467,781	482,034
Cash and cash equivalents at beginning of period	1,530,969	1,057,360
Cash and cash equivalents at end of period	1,063,188	1,539,394

(4) Notes to Financial Statements

(Notes on going concern assumption)

Not applicable.

(Notes on significant changes in shareholders' equity)

During the six months ended September 30, 2024, 4,650,000 shares of common stock were issued for total issue price of 299,250 thousand yen by execution of the series 16 warrants and 8,400,000 shares of common stock were issued for total issue price of 492,980 thousand yen by execution of the series 17 warrants to increase capital stock and legal capital surplus by 397,260 thousand yen each, including 1,534 thousand yen for the series 16 warrants and 756 thousand yen for the series 17 warrants transferred from share acquisition rights. As of September 30, 2024, capital stock was 1,047,921 thousand yen and capital surplus was 3,356,455 thousand yen.

(Significant subsequent events)

(Exercise of the series 17 warrants)

During the period from October 1, 2024 to November 8, 2024, 1,600,000 shares of common stock have been issued for total issue price of 72,700 thousand yen by execution of the series 17 warrants to increase capital stock and legal capital surplus by 36,422 thousand yen each, including 144 thousand yen transferred from share acquisition rights.