

Financial Results for the Fiscal Year ended March 31, 2021 [Japanese GAAP] (non-consolidated)

May 13, 2021

BrightPath Biotherapeutics Co., Ltd. Listed Market Mothers, TSE
TSE Code 4594 URL <https://www.brightpathbio.com/english/index.html>
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Scheduled date of annual meeting of stockholders : June 24, 2021
Scheduled date of dividend payment commencement : —
Scheduled date of submission of securities report : June 25, 2021
Supplementary materials for financial statements : Yes
Briefing of financial results : Yes (for analysts and institutional investors)

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

1. Financial results for fiscal year 2021 (April 1, 2020 – March 31, 2021)

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

	Net sales		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Fiscal year ended March 31, 2021	2	-77.8	-1,732	—	-1,738	—	-1,719	—
Fiscal year ended March 31, 2020	11	-92.7	-1,827	—	-1,823	—	-1,857	—

	Net income per share	Fully diluted net income per share	Return on shareholders' equity	Ratio of ordinary income to total assets	Operating margin
	Yen	Yen	%	%	%
Fiscal year ended March 31, 2021	-36.14	—	-51.4	-48.1	-69,188.5
Fiscal year ended March 31, 2020	-44.20	—	-45.3	-41.6	-16,170.4

(Note) 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	Net assets per share
	Million yen	Million yen	%	Yen
As of March 31, 2021	3,749	3,537	93.7	69.10
As of March 31, 2020	3,474	3,235	91.5	75.49

(Reference) Shareholders' equity As of March 31, 2021 3,511 million yen
As of March 31, 2020 3,178 million yen

(3) Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
	Million yen	Million yen	Million yen	Million yen
Fiscal year ended March 31, 2021	-1,769	-36	2,053	3,265
Fiscal year ended March 31, 2020	-1,784	-106	8	3,018

2. Dividends

	Annual dividends per share					Total dividends paid (annual)	Payout ratio	Ratio of dividends to net assets
	1Q	2Q	3Q	4Q	Annual			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal year ended March 31, 2020	—	0.00	—	0.00	0.00	—	—	—
Fiscal year ended March 31, 2021	—	0.00	—	0.00	0.00	—	—	—
Fiscal year ending March 31, 2022 (Forecast)	—	0.00	—	0.00	0.00	—	—	—

3. Projected financial results for fiscal year 2022 (April 1, 2021 – March 31, 2022)

(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	2	-20.1	-1,852	—	-1,852	—	-1,854	—	-36.49

(Note) The Company manages business results on an annual basis, and therefore only the full-year financial forecasts are disclosed.

[Notes]

(1) 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 |

(2) Number of shares outstanding (common stock)

1) Number of shares outstanding at the end of the period (including treasury stock)	As of March 31, 2021	50,817,500 shares	As of March 31, 2020	42,101,000 shares
2) Number of shares of treasury stock at the end of the period	As of March 31, 2021	— shares	As of March 31, 2020	— shares
3) Average number of shares during the period	Year ended March 31, 2021	47,581,918 shares	Year ended March 31, 2020	42,031,977 shares

* These financial results are outside the scope of audits by a certified public accountant or an audit corporation.

* 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 Operating Results, etc., (4) Future Outlook” on page 3 of the attachment.

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1. Overview of Operating Results, etc.

(1) Overview of Operating Results for the Fiscal Year under Review

During the fiscal year ended March 31, 2021, the Japanese economy as well as the global economies were heavily impacted by the global outbreak of the coronavirus disease (COVID-19) pandemic, and many nations went into lockdowns while Japan was subjected to repeated declarations of the state of emergency. Despite these setbacks, economic activities have gradually resumed in conjunction with the commencement of the vaccinations.

BrightPath Biotherapeutics Co., Ltd. (the “Company”) has been engaged in the new development of cancer immunotherapy drugs (drugs that treat cancer by utilizing the immune system which expels cancer).^{*1} Cancer immunotherapy drugs have brought about an innovation in cancer treatment which used to occur only around once in half a century and have become a major driver for the recent growth of the pharmaceutical market, as a whole. Work is continuing to expand the types of cancer indications of immune check point inhibitor antibodies,^{*2} which brought about this breakthrough and to apply them to diverse pharmaceuticals other than antibodies. However, there is still a long way to go in radically curing cancer and unmet medical needs remain largely untapped, with much room for further ongoing innovation in cancer immunotherapy by cancer immunotherapy drugs, which use a scientifically proven mechanism for cancer treatment. In this development field, the Company has been simultaneously developing pipelines of drug types such as cancer vaccines, cell therapy agents, and antibody drugs in various stages ranging from basic research to clinical trials.

A pipeline currently under clinical trial is the cancer peptide vaccine (GRN-1201). A phase II clinical trial of the vaccine in combination with immune check point inhibitor antibody *Pembrolizumab* is currently underway in the US for non-small cell lung cancer (NSCLC).

In June 2020, an investigator-initiated clinical trial began for induced pluripotent stem cells (iPSC) derived regenerating natural killer T-cell (NKT cell) therapy (iPS-NKT) targeting head and neck cancer. This clinical trial is led by RIKEN and National University Corporation Chiba University. In the cell therapy agent pipeline, the HER2 chimeric antigen receptor (CAR) T cell (CAR-T cell) therapy (BP2301) licensed from National University Corporation Shinshu University is in preparation for beginning clinical trials.

In the antibodies pipeline, following the success of PD-1/PD-L1, the Company is working to develop antibodies that inhibit target molecules serving as immune check point proteins regarding the exhaustion and suppression of T cells, the efficacy of which are in the process of being proven scientifically.

Additionally, the Company is conducting joint studies with the National Research and Development Agency National Cancer Center Japan to utilize antigen prediction algorithms used in the design of neoantigen vaccines to identify COVID-19 viral antigens.

As a result, for the fiscal year ended March 31, 2021, we recorded 1,732,802 thousand yen as operating loss (operating loss of 1,827,349 thousand yen in the previous fiscal year), 1,738,636 thousand yen as ordinary loss (ordinary loss of 1,823,996 thousand yen in the previous fiscal year), and net loss of 1,719,634 thousand yen (net loss of 1,857,774 thousand yen in the previous fiscal year).

(2) Overview of Financial Position for the Fiscal Year under Review

At the end of the fiscal year under review, assets were 3,749,428 thousand yen, an increase of 274,789 thousand yen from the end of the previous fiscal year. The main factors for this include an increase of 247,031 thousand yen in cash and deposits, primarily due to financings for the exercise of share acquisition rights exceeding expenditures related to research and development, etc.

Liabilities were 211,785 thousand yen, a decrease of 27,615 thousand yen from the end of the previous fiscal year. The main factors for this include a decrease of 15,847 thousand yen in accounts payable – other due to a decrease in expenditures related to research and development, etc.

Net assets were 3,537,642 thousand yen, an increase of 302,405 thousand yen from the end of the previous fiscal year. The main factors for this are the increase of 1,026,500 thousand yen in capital stock and capital surplus, respectively, and the recording of a net loss of 1,719,634 thousand yen.

As a result of the above, equity ratio was 93.7% compared to 91.5% at the end of the previous fiscal year.

(3) Overview of Cash Flows for the Fiscal Year under Review

At the end of the fiscal year under review, cash and cash equivalents (hereinafter “net cash”) amounted to 3,265,388 thousand yen, an increase of 247,031 thousand yen from the end of the previous fiscal year. The situation of each cash flow for the fiscal year under review and the underlying factors are as follows:

(Cash flows from operating activities)

Net cash used in operating activities amounted to 1,769,848 thousand yen (1,784,461 thousand yen used in the previous fiscal year). This was mainly due to recording loss before income taxes of 1,717,214 thousand yen.

(Cash flows from investing activities)

Net cash used in investing activities amounted to 36,211 thousand yen (106,879 thousand yen used in the previous fiscal year). This was mainly due to 34,920 thousand yen spent for purchase of property, plant and equipment associated with research and development equipment, etc.

(Cash flows from financing activities)

Net cash provided from financing activities amounted to 2,053,090 thousand yen (8,521 thousand yen provided in the previous fiscal year). This was mainly due to 2,052,505 thousand yen in proceeds from issuance of shares resulting from exercise of share acquisition rights.

(4) Future Outlook

The Company specializes in the field of cancer immunotherapy drugs, and has developed cancer vaccines since its foundation. With the new addition of cell therapy agents and antibody drugs, the Company will work on drug candidates in these three modalities (drug types), under a business model that covers the process from basic research to clinical trials, followed by licensing out.

The cancer peptide vaccine (GRN-1201) targeting NSCLC for use in combination with immune check point inhibitors is currently under phase II clinical trial in the US. Upon accumulating a certain number of cases, an interim assessment will be made, and if the target response rates are attained, more cases will be accumulated. Despite the status of the COVID-19 pandemic in the US, clinical trials are continuing without suspensions or cancellations. However, case registrations seem to be taking a long time.

iPS-NKT, whose phase I clinical trial (investigator-initiated) has commenced, is an allogeneic cell therapy agent using regenerated NKT cells derived from iPS cells to treat solid tumors. This development project, which was initially led by RIKEN and National University Corporation Chiba University, has become a joint study with the participation by the Company from 2018, and the Company retains the option to license in the right to exclusive development, manufacturing, and marketing of iPS-NKT cell therapy. The Company is supporting this investigator-initiated clinical trial while improving the manufacturing process with an eye to the sponsor-initiated trials following this investigator-initiated trial.

BP2301 is a chimeric antigen receptor T cell (HER2 CAR-T cell) therapy that recognizes HER2 antigens that are highly expressed in various solid tumors. The Company, together with Professor Yozo Nakazawa of Shinshu University and Assistant Professor Shigeki Yagyu of Kyoto Prefectural University of Medicine, jointly developed a new CAR-T cell culture method and by combining this method with Professor Nakazawa’s non-viral gene transfer method, succeeded in producing young memory T cells, long-lived in vivo, that may achieve long-term persistence of anti-tumor effects. Preparations are underway for clinical trials that target osteosarcoma, a type of pediatric cancer, as the first type of cancer to be targeted by this therapy.

BP1101, which is in pre-clinical trials, is a fully-personalized neoantigen vaccine^{*3} inducing cancer immunity against antigens derived from cancer-specific genetic mutations (neoantigens). As tumor mutation burden (number of neoantigens) and response to the immune check point antibody therapy correlate, the antibody is deemed to enhance the antitumor effect of T cells, which identify neoantigens as cancer markers through this antibody. Since these neoantigens are completely unique to every individual patient, this neoantigen-based approach involves individualized therapy. In other words, patients receive personalized neoantigen vaccines tailored to each of them. Such personalized vaccination requires a development approach totally different from conventional mass-produced drugs intended for multiple patients in a predefined group. BP1209, a next-generation version of BP1101, is a dendritic cell marker-antibody conjugate vaccine that has enhanced the

delivery of neoantigen vaccines to the lymph nodes where dendritic cells and T cells are associated so that the administered neoantigen vaccines efficiently stimulate the T cells in vivo. The Company is continuing its basic research.

BP1401, which is also in the pre-clinical trial phase, is a TLR9 Agonist which stimulates the TLR9 receptors of dendritic cells to facilitate the active functioning of T cells with antitumor response in a strongly immunosuppressive tumor microenvironment. It attempts to turn a “cold tumor,” characterized by the absence of T cells that attack cancer cells at the tumor site, into a “hot tumor,” in which many T cells exist.

Antibody drug pipelines are at the basic research phase and multiple antibodies including BP1200 (anti-CD73 antibody) and BP1210 (anti-TIM-3 antibody) that aim to achieve cancer immunity are being developed. The Company is continuing its efforts with the aim of licensing out these antibodies.

As a result of the above, for the fiscal year ending March 31, 2022, we are planning research and development costs of 1,515 million yen to further promote research and development, and expecting an operating loss of 1,852 million yen, ordinary loss of 1,852 million yen, and net loss of 1,854 million yen.

<Glossary>

*1 cancer immunotherapy

Cancer immunotherapy evokes and increases the immune reaction against cancer cells (cancer immunity) to kill cancer cells, reduce tumors, suppress progression/metastasis and prevent a recurrence.

*2 immune check point inhibitor antibodies

Cancer cells have a mechanism to suppress the immune system and evade the anticancer response of immune cells through molecules called immune check points. Antibody drugs inhibit immune check points to block this suppression and enhance immune reactions to cancer cells.

*3 fully personalized neoantigen cancer vaccine

Cancer vaccines tailored to match the neoantigens found on cancer cells of individual patients. Clinical trials are performed overseas by academia and preceding development companies.

2. Basic Stance on Choice of Accounting Standards

The Company applies accounting principles generally accepted in Japan (Japanese GAAP), and will appropriately consider the adoption of International Financial Reporting Standards (IFRS) in line with various conditions in Japan and overseas in the future.

3. Financial Statements and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of March 31, 2020	As of March 31, 2021
Assets		
Current assets		
Cash and deposits	3,018,356	3,265,388
Accounts receivable - trade	659	283
Other	309,169	385,321
Total current assets	3,328,186	3,650,992
Non-current assets		
Property, plant and equipment		
Buildings, net	0	0
Machinery and equipment, net	0	0
Tools, furniture and fixtures, net	97,156	48,201
Total property, plant and equipment	97,156	48,201
Intangible assets		
Software	0	0
Total intangible assets	0	0
Investments and other assets		
Long-term prepaid expenses	0	0
Other	49,296	50,234
Total investments and other assets	49,296	50,234
Total non-current assets	146,452	98,435
Total assets	3,474,639	3,749,428

(Thousands of yen)

	As of March 31, 2020	As of March 31, 2021
Liabilities		
Current liabilities		
Accounts payable - trade	814	468
Accounts payable - other	128,261	112,413
Accrued expenses	1,661	6,662
Income taxes payable	34,158	31,998
Advances received	976	8
Deposits received	6,989	4,853
Total current liabilities	172,862	156,405
Non-current liabilities		
Deferred tax liabilities	0	0
Provision for retirement benefits	44,254	33,005
Asset retirement obligations	22,285	22,374
Total non-current liabilities	66,539	55,379
Total liabilities	239,401	211,785
Net assets		
Shareholders' equity		
Capital stock	5,433,211	6,459,712
Capital surplus		
Legal capital surplus	5,416,796	6,443,296
Total capital surpluses	5,416,796	6,443,296
Retained earnings		
Other retained earnings		
Retained earnings brought forward	-7,671,989	-9,391,623
Total retained earnings	-7,671,989	-9,391,623
Total shareholders' equity	3,178,018	3,511,385
Share acquisition rights	57,219	26,257
Total net assets	3,235,237	3,537,642
Total liabilities and net assets	3,474,639	3,749,428

(2) Statements of Operations

(Thousands of yen)

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
Net sales		
Revenue from research and development	3,800	2,504
Net sales of goods	7,500	-
Total net sales	11,300	2,504
Cost of sales		
Research and development costs	1,467	1,145
Cost of goods sold		
Cost of purchased goods	3,000	-
Total	3,000	-
Cost of goods sold	3,000	-
Total cost of sales	4,467	1,145
Gross profit	6,832	1,358
Selling, general and administrative expenses	1,834,182	1,734,161
Operating income	-1,827,349	-1,732,802
Non-operating income		
Interest income	42	35
Foreign exchange gains	3,009	3,131
Other	357	98
Total non-operating income	3,409	3,265
Non-operating expenses		
Miscellaneous loss	56	0
Share issuance cost	-	9,099
Total non-operating expenses	56	9,099
Ordinary income	-1,823,996	-1,738,636
Extraordinary profit		
Gain on reversal of share acquisition rights	12,454	31,051
Gain on sales of non-current assets	95	-
Total extraordinary profit	12,550	31,051
Extraordinary losses		
Loss on sales of non-current assets	255	-
Impairment loss	48,159	9,629
Other	-	0
Total extraordinary losses	48,415	9,629
Income before income taxes	-1,859,861	-1,717,214
Income taxes - current	2,732	2,420
Income taxes - deferred	-4,819	-
Total income taxes	-2,087	2,420
Net income	-1,857,774	-1,719,634

Manufacturing Statement

1. Manufacturing statement for research and development costs

Category	Notes	Fiscal year ended March 31, 2020		Fiscal year ended March 31, 2021	
		Amount (Thousand yen)	Composition (%)	Amount (Thousand yen)	Composition (%)
I. Material cost		—	—	—	—
II Labor cost		—	—	—	—
III Expenses	*1	1,467	100.0	1,145	100.0
Research and development expenses for the current period		1,467	100.0	1,145	100.0
Work in progress at the beginning of the period		—		—	
Total		1,467		1,145	
Transfer to other account		—		—	
Research and development costs for the current period		1,467		1,145	

(Note) *1 Main breakdown is as follows:

Item	(Thousand yen)	
	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
Outsourcing expenses	720	720

(Cost accounting method)

The Company adopts the job-order cost system.

(3) Statement of Changes in Net Assets

Fiscal year ended March 31, 2020 (From April 1, 2019 to March 31, 2020)

(Thousands of yen)

	Shareholders' equity					Total shareholders' equity	Share acquisition rights	Total net assets
	Capital stock	Capital assets surplus		Retained earnings				
		Legal capital surplus	Total capital surplus	Other retained earnings	Total retained earnings			
				Retained earnings brought forward				
Balance at beginning of current period	5,427,836	5,411,421	5,411,421	-5,814,215	-5,814,215	5,025,042	71,029	5,096,072
Changes of items during period								
Issuance of new shares	5,375	5,375	5,375			10,750		10,750
Net loss				-1,857,774	-1,857,774	-1,857,774		-1,857,774
Net changes of items other than shareholders' equity							-13,810	-13,810
Total changes of items during period	5,375	5,375	5,375	-1,857,774	-1,857,774	-1,847,024	-13,810	-1,860,834
Balance at end of current period	5,433,211	5,416,796	5,416,796	-7,671,989	-7,671,989	3,178,018	57,219	3,235,237

Fiscal year ended March 31, 2021 (From April 1, 2020 to March 31, 2021)

(Thousands of yen)

	Shareholders' equity					Total shareholders' equity	Share acquisition rights	Total net assets
	Capital stock	Capital assets surplus		Retained earnings				
		Legal capital surplus	Total capital surplus	Other retained earnings	Total retained earnings			
				Retained earnings brought forward				
Balance at beginning of current period	5,433,211	5,416,796	5,416,796	-7,671,989	-7,671,989	3,178,018	57,219	3,235,237
Changes of items during period								
Issuance of new shares	1,026,500	1,026,500	1,026,500			2,053,001		2,053,001
Net loss				-1,719,634	-1,719,634	-1,719,634		-1,719,634
Net changes of items other than shareholders' equity							-30,961	-30,961
Total changes of items during period	1,026,500	1,026,500	1,026,500	-1,719,634	-1,719,634	333,366	-30,961	302,405
Balance at end of current period	6,459,712	6,443,296	6,443,296	-9,391,623	-9,391,623	3,511,385	26,257	3,537,642

(4) Statements of Cash Flows

(Thousands of yen)

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
Cash flows from operating activities		
Loss before income taxes	-1,859,861	-1,717,214
Depreciation	62,471	66,688
Share-based compensation expenses	872	—
Impairment loss	48,159	9,629
Gain on reversal of share acquisition rights	-12,454	-31,051
Increase (decrease) in retirement benefit liability	11,112	-11,249
Interest and dividend income	-42	-35
Decrease (increase) in notes and accounts receivable - trade	181	376
Increase (decrease) in notes and accounts payable - trade	-27,519	-346
Increase (decrease) in advances received	-967	-967
Other, net	-4,329	-82,980
Subtotal	-1,782,376	-1,767,150
Interest and dividend income received	42	35
Income taxes paid	-2,127	-2,732
Net cash provided by (used in) operating activities	-1,784,461	-1,769,848
Cash flows from investing activities		
Purchase of property, plant and equipment	-107,282	-34,920
Purchase of intangible assets	-2,850	-354
Proceeds from sales of property, plant and equipment	495	—
Payments for guarantee deposits	—	-937
Proceeds from collection of guarantee deposits	2,758	—
Net cash provided by (used in) investing activities	-106,879	-36,211
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	10,750	2,052,505
Repurchase of share acquisition rights	-2,228	—
Proceeds from issuance of share acquisition rights	—	585
Net cash provided by (used in) financing activities	8,521	2,053,090
Net increase (decrease) in cash and cash equivalents	-1,882,820	247,031
Cash and cash equivalents at beginning of period	4,901,177	3,018,356
Cash and cash equivalents at end of period	3,018,356	3,265,388

(5) Notes to Financial Statements
 (Notes on going concern assumption)
 Not applicable.

(Statement of cash flows)
 Details of significant no-cash transactions
 Asset retirement obligations

	(Thousands of yen)	
	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
Significant asset retirement obligations recorded	583	—

(Segment information, etc.)

Segment information is omitted as the Company operates in the single business segment of the pharmaceutical development business and there is no other significant segment information.

(Per share information)

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
	Yen	Yen
Net assets per share	75.49	69.10
Net loss per share	-44.20	-36.14

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

2. The basis for calculating net loss per share is as follows:

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
Net loss (Thousands of yen)	-1,857,774	-1,719,634
Amount not attributable to common shareholders (Thousand yen)	—	—
Net loss for common stock (Thousand yen)	-1,857,774	-1,719,634
Average number of shares of common stock during the period (Shares)	42,031,977	47,581,918
Overview of residual shares not included in calculation of fully diluted net income per share due to lack of dilutive effect	—	—

3. The basis for calculating net assets per share is as follows:

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021
Total net assets (Thousand yen)	3,235,237	3,537,642
Amount deducted from total net assets (Thousand yen)	57,219	26,257
(of which, share acquisition rights) (Thousand yen)	-57,219	-26,257
Net assets at the end of the period for common stock (Thousand yen)	3,178,018	3,511,385
Number of shares of common stock at the end of the period to calculate net assets per share (Shares)	42,101,000	50,817,500

(Significant subsequent events)
 Not applicable.