(Commencement of electronic provision measures: March 9, 2023)

To Our Shareholders:

2-12-10 Shiba-Daimon, Minato-ku, Tokyo

Noile-Immune Biotech, Inc.

Koji Tamada, President & CEO

Notice of the 8th Ordinary General Meeting of Shareholders

Dear Shareholders:

We would like to express our sincere gratitude for your continued support and patronage. This is to notify you that the 8th Ordinary General Meeting of Shareholders of Noile-Immune Biotech, Inc. (the "Company") will be held for the purposes outlined below.

To facilitate the electronic provision of this General Meeting of Shareholders, all the relevant reference documents are now available on the Company website under the heading "NOTICE OF THE 8th ORDINARY GENERAL MEETING OF SHAREHOLDERS" at https://www.noile-immune.com/ir/stock/meeting.html.

In light of the ongoing COVID-19 pandemic, shareholders are requested to refrain from attending the physical venue for the General Meeting of Shareholders. You are encouraged to exercise your voting rights by completing the enclosed Voting Instruction Form. Kindly review the accompanying Reference Documents for the General Meeting of Shareholders, indicate your approval or disapproval of the proposals in the enclosed Voting Instruction Form, sign or affix your name and seal, and return it by post. Please ensure the Voting Instruction Form will be received by us <u>no later than 5:00 pm on Wednesday, March 29, 2023</u>.

Yours Sincerely,

[Notice]

Date March 30, 2023 (Thursday) 3:00 p.m.
 Location 2-12-10 Shiba-Daimon, Minato-ku, Tokyo T&G Hamamatsucho Building 5th Floor

Noile-Immune Biotech, Inc. Meeting Room at Headquarters

3. Agenda of the Meeting

Matters to be reported: The 8th Fiscal Year Business and Financial Statements

(January 1, 2022 to December 31, 2022)

Matters to be resolved: Election of Four (4) Directors

Details of the agenda can be found in the "Reference Documents for the General Meeting of Shareholders".

4. Treatment of Voting Rights

If neither approval nor disapproval of each proposal is indicated on the Voting Instruction Form, the

(End of document	ıt)
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If amendments to the Electronic Provision Measures Matters are to be taken arise, a notice of the	
amendments and the details of the matters before and after the amendments will be posted on the Company	's
aforementioned website.	

Company will deem that you indicated your approval of the proposal.

(Commencement of electronic provision measures: March 9, 2023)

To Our Shareholders:

Information on Live Streaming of the General Shareholders' Meeting

In light of the current COVID-19 situation, we kindly request that you exercise your voting rights by

submitting a Voting Instruction Form instead of attending the physical venue for the General Meeting

of Shareholders, regardless of your state of health.

The General Meeting of Shareholders will be live-streamed on the internet to ensure your

participation in the meeting. Prior application is required to view the Shareholders' Meeting via the

internet, so kindly complete the application in accordance with the following procedure:

[How to Apply for Live Streaming]

Please send your application via email to admin@noile-immune.com by the following deadline.

Application deadline: Monday, March 27, 2023, 5:00 p.m.

Email title: Live Streaming of the General Shareholders' Meeting

Email message (Please be assured to provide the following two items):

1. Your address

2. Your name (corporate name and representative name for the corporation)

(end of document)

# **Voting Instruction Form**

To:	Noile-	Immune	Biotech,	Inc
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I hereby exercise my voting rights for the 8th Ordinary General Meeting of Shareholders of Noile-Immune Biotech, Inc. scheduled for March 30, 2023, including any continued or adjourned meetings. I indicate my vote by circling either "Approve" or "Disapprove" for each matter submitted for resolution, as shown below:

Number of voting rights exercised	Vote(	s)	)

Matters to be resolved	Approval or Disapproval
Proposal	Approval / Disapproval (Excluding)

Date:

Your Address:

Your Name:

Note: Please indicate your vote for or against each proposal on the Voting Instruction Form and return it to us **by 5:00 pm on Wednesday, March 29, 2023.** 

If neither approval nor disapproval of a proposal is indicated, it shall be deemed a vote of approval for Company proposals.

# Reference Documents for the General Meeting of Shareholders

[Proposal and Reference Information]

Proposal: Election of Four (4) Directors

The Company seeks approval for the election of four directors whose terms of office expire in accordance with Article 21 (Term of Office of Directors) of the Articles of Association.

The following candidates have already given their consent to this proposal.

Name		Number of the
(Date of birth)	Career summary, positions and areas of responsibility	Company's
(Date of offili)		shares owned
Koji Tamada (March 28, 1968)	Jun 1992: Joined Kyushu University Hospital Apr 1998: Postdoctoral Researcher of Mayo Clinic, Minnesota, USA Oct 2002: Assistant Professor of Mayo Clinic, Minnesota, USA Aug 2005: Assistant Professor of Johns Hopkins University, Maryland, USA Sep 2009: Associate Professor of Cancer Center, University of Maryland, USA May 2011: Professor of Yamaguchi University Graduate School of Medicine, Department of Immunology (to present) Mar 2016: Director of Noile-Immune biotech, Inc. Sep 2020: President & CEO of Noile-Immune Biotech, Inc. (to present)	3,750,000 shares
	(Significant concurrent position)  Professor of Yamaguchi University Graduate School of Medicine,  Department of Immunology	
Tsutomu Tokashiki (December 14, 1981)	June 2006: Joined Onco Therapy Science, Inc.  Dec 2014: President of Reading Valley Co.  Jul 2015: Joined Noile-Immune Biotech, Inc.  Jan 2018: General Manager of Corporate Planning Dept.,  Business Administration Headquarters of Noile-Immune Biotech,  Inc.  May 2019: Director of Noile-Immune Biotech, Inc. (to present)  Jun 2019: General Manager of Business Division and Manager of  Business Planning Dept. of Noile-Immune Biotech, Inc.  Jan 2020: Manager of Business Planning Research Dept. of Noile-Immune Biotech, Inc. (to present)	25,000 shares
Philippe Fauchet (November 2, 1957)	Jun 2001: President & CEO of Sanofi Santelabo K.K. (current Sanofi K.K.)  May 2005: President & CEO of Sanofi-Aventis K.K. (current Sanofi K.K.)	_

	Jan 2010: President & CEO of GlaxoSmithKline K.K.	
	Apr 2017: Chairman of GlaxoSmithKline K.K.	
	May 2019: External Director of BONAC Corporation	
	Mar 2020: Director of Noile-Immune Biotech, Inc. (to present)	
	Sep 2020: External Director of Rezolute Inc. (to present)	
	Jun 2022: External Director of LUCA Science Inc. (to present)	
	Jun 2022: External Director of JCR Pharmaceuticals Co., Ltd. (to	
	present)	
	(Significant concurrent position)	
	External Directors of Rezolute Inc.	
	External Director of LUCA Science Inc.	
	External Director of JCR Pharmaceuticals Co., Ltd.	
	Apr 1999: Joined Nagano & Morita CPA	
II' 1 N	Feb 2004: Joined Ernst and Young Global Financial Service	
Hiroko Nagai	Oct 2010: Launched Hiroko Nagai CPA Office	
(October 5, 1976)	Mar 2020: Joined Noile-Immune Biotech, Inc. and became	_
	Manager of Administrative Dept. (to present)	
	Jun 2020: Director of Noile-Immune Biotech, Inc. (to present)	

(Notes) 1. Each candidate has no special conflicts of interest with the Company.

- 2. Mr. Philippe Fauchet is a candidate for external director.
- 3. The Company nominates Mr. Philippe Fauchet as a candidate for external director because of his abundant knowledge and insights into the pharmaceutical industry and corporate management. We expect him to provide helpful advice for the management of the Company.
- 4. Mr. Philippe Fauchet was appointed as an outside director of the Company in March 2020, which will have been for three years after the General Meeting of Shareholders.
- 5. The Company has concluded a Directors' and Officers' liability insurance policy with an insurance company, pursuant to Article 430-3, Paragraph 1 of the Companies Act. This insurance policy covers damages that may arise when a claim for damages is made against the insured director or auditor, etc. during the term of the policy due to duties performed by the insured person as a director or an auditor, etc. (However, this shall not apply in cases where damage is caused intentionally knowing that the act may result in damage.) If each candidate is elected as a Director of the Company pursuant to this proposal, they will be insured under the relevant insurance. The Company plans to renew the contract with the same contents at the next renewal.
- 6. The Company has designated Mr. Philippe Fauchet as an independent director as stipulated by the Tokyo Stock Exchange and plans to extend the designation subject to his reelection.

# The 8th Fiscal Year

**Business Report** 

From January 1, 2022 To December 31, 2022

Noile-Immune Biotech, Inc.

2-12-10 Shiba-Daimon, Minato-ku, Tokyo

## **Business Report**

From January 1, 2022 To December 31, 2022

- 1. Current Status of the Company
- (1) Business summary for the fiscal year ended December 31, 2022
  - (a) Outline and results of business operations

## The Company's core technology

Proliferation-Inducing and Migration-Enhancing ("PRIME") technology, our core technology, is a highly promising platform technology that may overcome limitations of Chimeric Antigen Receptor-T ("CAR-T") cell therapy which has yet to be proven to be efficacious in treating solid tumors. The PRIME Technology is expected to suppress solid tumor growth effectively and sustainably as it can accumulate CAR-T cells and the host's immunocompetent cells, including T cells and dendritic cells, in solid tumor, improve the functions of the accumulated cells, and build immune memory against cancer cells in part of those cells. We concluded an exclusive license agreement concerning the patent for the PRIME technology with Yamaguchi University on October 1, 2015, and Koji Tamada, President and CEO of the Company, and his research team published details of the technology in *Nature Biotechnology**.

*IL-7 and CCL19 expression in CAR-T cells improves immune cell infiltration and CAR-T cell survival in the tumor. Adachi K, Kano Y, Nagai T, Okuyama N, Sakoda Y, Tamada K. Nat Biotechnol. 2018 Apr;36(4):346-351. doi: 10.1038/nbt.4086. Epub 2018 Mar 5.

#### Research and development

The Company is currently conducting Phase I clinical trial of NIB101, one of our original drug development pipelines using the PRIME technology, (ClinicalTrials.gov Identifier: NCT05192174), and working on identification of target cases. We are also working on the research of another new pipelines and the next-generation technologies. In the joint research with Yamaguchi University since 2017, we have continued to work on next-generation gene-modified cell therapies mainly using CART and TCR-T, cancer immunotherapy using allogeneic cells, and the next-generation PRIME technology.

## [Business alliance]

We entered into an agreement with Takeda Pharmaceutical Company Limited ("Takeda") in December 2018 to license our pipelines NIB102 (development pipeline code in Takeda: TAK-102) and NIB103 (development pipeline code in Takeda: TAK-103) using the PRIME technology, and these pipelines are currently under Phase I clinical trial. In November 2022, Takeda gave a poster presentation for the interim results of NIB102 at the 37th Annual Meeting of the Society for

Immunotherapy of Cancer, demonstrating encouraging results in the preliminary data in terms of safety, cellular kinetics and pharmacodynamic considerations, and the dose-escalation study is ongoing.

We have also continued to work on the research and development of next-generation SPEAR T-cell using the PRIME technology with Adaptimmune Therapeutics plc and of next-generation CAR-T cell therapies using the PRIME technology with Autolus Therapeutics plc, both started in 2019. In August 2022, we entered into an agreement to grant a license of the PRIME technology to Chugai Pharmaceutical Co., Ltd. based on the research on the technology assessment with the company since 2020. In October 2021, we entered into an alliance agreement regarding technology assessment with DAIICHI SANKYO COMPANY, LIMITED, and the assessment of the PRIME technology is still ongoing. We have also continued to work on the joint development with Shibuya Corporation which started in 2019 to establish the automated cell manufacturing system aiming at mass production and stable supply of CAR-T cells at a reduced cost.

## [Patent]

The patent applications for which we have obtained an exclusive license from Yamaguchi University (PCT/JP2015/05080) are in the process of securing patent rights in various countries including Japan, the U.S. and Europe. We are also filing patent applications and securing patents based on findings of applied research based on that technology.

As a result, for the fiscal year ended December 31, 2022, the Company recorded operating revenue of \(\pm\)625,783 thousand (up 521.2% year-on-year), operating loss of \(\pm\)106,345 thousand (\(\pm\)767,511 thousand of operating loss for FY2021), ordinary loss of \(\pm\)384,202 thousand (\(\pm\)792,615 thousand of ordinary loss for FY2021) due to recognition of listing expenses of \(\pm\)268,210 thousand, and net loss of \(\pm\)386,622 thousand (\(\pm\)795,035 thousand of net loss for FY2021).

#### (b) Funding status

The Company issued 621,200 shares through a third-party allotment to MEDIPAL Innovation Investment Limited Partnership with the payment date of August 31, 2022 and raised ¥500,066 thousand.

- (c) Capital expenditure

  Not applicable.
- (d) Business transfers, absorption-type splits, or incorporation-type splits Not applicable.
- (e) Businesses transferred from other companies

Not applicable.

- (f) Rights and obligations related to other companies' businesses assumed as a result of absorptiontype mergers or splits Not applicable.
- (g) Acquisition or disposition of shares, other equity interests, or subscription rights to shares of other companies

Not applicable.

### (2) Assets and Profit or Loss

Period Items	5th Fiscal Year (Ended December	6th Fiscal Year (Ended December 31, 2020)	7th Fiscal Year (Ended December 31, 2021)	8th Fiscal Year (Ended December 31, 2022)
Operating revenue (thousands of yen)	31, 2019) 521,004	97,277	100,732	625,783
Ordinary income (loss) (thousands of yen)	56,906	(604,610)	(792,615)	(384,202)
Net income (loss) (thousands of yen)	55,086	(636,649)	(795,035)	(386,622)
Net income (loss) per share (yen)	1.60	(17.93)	(20.75)	(9.87)
Total assets (thousands of yen)	2,338,973	2,674,261	4,271,049	4,641,032
Net assets (thousands of yen)	2,235,032	2,598,379	4,185,334	4,300,617
Net assets per share (yen)	64.67	72.24	107.30	108.48

- (Notes) 1. The Company effected a ten-for-one stock split of its common stock on June 30, 2019 and a five-for-one stock split of its common stock on November 11, 2021. Net income (loss) per share and net assets per share are calculated assuming that stock split had been implemented on January 1, 2019.
  - 2. Figures for the 6th fiscal year were restated due to corrections of errors, etc.
- (3) Current status of major parent company and subsidiaries
  - (a) Parent company
    Not applicable.
  - (b) Major subsidiaries
    Not applicable.

#### (4) Issues to be addressed

The Company recognizes the following matters as issues to be addressed.

(a) Expansion of basic research system for the PRIME technology and promotion of joint research and development with academic and private institutions in Japan and overseas

We have built up multiple pipelines through joint research with Yamaguchi University. We are also conducting basic research on the improvement and application of our core PRIME technology. We will enhance our research system so as to further increase pipelines and create intellectual property related to the PRIME technology in close cooperation with Yamaguchi University and through joint research and development with academic and private institutions in Japan and overseas.

### (b) Promotion of clinical trials

We have built up several pipelines. We believe our effort to promote clinical trials of these pipelines on our own initiative and assess the data obtained from such trials can also accelerate the development at our licensees. We will steadily proceed with the clinical trials of NIB101, which is at the most advanced stage among our original pipelines.

#### (c) Support for our licensees

We plan to continuously cooperate with the pharmaceutical companies to whom we have granted a license for the PRIME technology by providing technical advice or sharing work under some agreements, to facilitate clinical development.

#### (d) Enhancement of our systems to increase licensing agreements

We aim to secure talented personnel in order to build stable business portfolio and obtain further revenue opportunity as well as to find more pharmaceutical companies in Japan and overseas to enter into licensing agreements with for our "Co-pipeline" business.

## (e) New cooperation with external institutions to obtain new business opportunities

We aim to expand pipelines as well as build new forms of pipelines and improve efficiency of cellular medicine manufacturing. To that end, we are trying to expand cooperation with external institutions having technologies such as new genome editing technologies, gene transfer methods and automated cell cultivation equipment.

### (f) Enhancement of financial base

We have raised funds through multiple equity financing and licensing fees from several partner companies, and we will enhance financial base by raising funds at an appropriate time as needed to further promote research and development in the future.

## (g) Recruitment, development and promotion of the Company's full-time employees

Our basic policy is to operate our principal business with our full-time employees. It is because we believe the fact that our team members who truly empathize with the Company's corporate philosophy proactively work on research and development or work with our licensees will enhance the quality and speed of the business promotion and significantly differentiate ourselves from our competitors, giving us the biggest competitive advantage in the industry.

In recruiting new employees, we evaluate and screen candidates based on their background, ability, and potential, and, at the final interview, explain our corporate philosophy and see whether they can empathize with it. In terms of the development after they join the Company, we provide them with on-the-job training from supervisors and other trainings based on the personalized education and training schedule prepared by the head of the department.

Employees' assignment, promotion, pay raise, demotion, and pay reduction are determined based on the assessment of each employee's performance using the individual goal management sheet prepared in advance and also on the assessment by the Human Resources Evaluation Committee of whether their daily behaviors have been in line with the Company's corporate philosophy.

Based on the above method, we will strive to secure appropriate and sufficient human resources as needed according to the acceleration in research and development and the progress of pipelines.

#### (5) Principal business (as of December 31, 2022)

We have been conducting research and development of the next-generation cancer immunotherapy, called Chimeric Antigen Receptor ("CAR") -T therapy, which is expected to demonstrate antitumor efficacy as CAR-T cells that carry genes encoding antibody fragments binding to tumor-specific antigens and the sequence necessary to activate T cells administered to cancer patients will identify and attack cancer antigen on the surface of cancer cells inside the patients' body. In recent years, the number of clinical trials for CAR-T cell therapies has been growing rapidly worldwide, and several products were also approved in Japan since 2019.

While progress has been made in application of the CAR-T cell therapy to hematologic cancers, the effective CAR-T cell therapy for solid tumors, which account for over 90 % of all cancer cases, has yet to be established. In order to address this issue, we have been conducting research on the PRIME technology, which can be the core technology for CAR-T cell products that are effective for solid tumors and promoting clinical development of CAR-T cell therapies using such technology. In terms of clinical development, we promote the original drug development business in which we develop CAR-T cell products using the PRIME technology in-house and license them to pharmaceutical companies, and the co-pipeline business in which we license the PRIME technology and develop CAR-T/TCR-T cell products using the PRIME technology jointly with partners.

## (6) Major offices (as of December 31, 2022)

Name	Location
Headquarters	Minato-ku, Tokyo
Shonan Research Center	Fujisawa, Kanagawa
Yamaguchi University Laboratory	Ube, Yamaguchi

## (7) Employees (as of December 31, 2022)

Number of employees	Changes from the previous year-end	Average age	Average service years	
19	Increase by 5	49.0 years old	2 years 1 month	ĺ

(Notes)1. Number of employees represents full-time employees.

- 2. The increase in the number of employees is mainly associated with the establishment of a management system to prepare for the stock listing.
- (8) Major lenders and the amount of borrowings (as of December 31, 2022)

  Not applicable.
- (9) Other material matters regarding the current status of the Company Not applicable.

2. Status of Shares (as of December 31, 2022)

(1) Total number of authorized shares: 155,800,000 shares

(2) Total number of shares issued and outstanding: 39,579,865 shares

(3) Number of shareholders: 34

## (4) Major shareholders (Top 10)

Name of shareholders	Number of shares owned (shares)	Stock ownership ratio (%)
Tsurukame Co., Ltd.	9,871,350	24.94
Takeda Pharmaceutical Company Limited	8,119,800	20.51
Koji Tamada	3,750,000	9.47
Binex Co., Ltd.	2,277,825	5.75
Hidenobu Ishizaki	2,000,000	5.05
Satoshi Wada	2,000,000	5.05
Kyoko Seto	2,000,000	5.05
Daiwa Taiwan-Japan Biotech Fund	1,349,200	3.40
Apricot Co., Ltd.	1,203,850	3.04
Yukimi Sakota	1,000,000	2.52

(Notes) 1. The Company does not own treasury stock.

## (5) Other material matters regarding shares

Not applicable.

^{2.} Stock ownership ratio is rounded down to two decimal places.

## 3. Subscription Rights to Shares

# (1) Subscription rights to shares held by the Company's officers, etc. as of December 31, 2022

1 0		<u> </u>			
Name of subscription rights to shares  Date of resolution to issue  Number of subscription rights to shares (units)					rights to shares ound)
		March 2	29, 2017	August 10, 2018	
		154 (1	Note) 1	69 (N	Vote) 1
Class and	d number of underlying	Commo	on stock	Commo	on stock
S	shares (shares)	770,000	(Note) 1	345,000	(Note) 1
Cash payment for subscription rights to shares (yen per unit)		10,	800		0
Exercise price (yen per share)		1	00	2.	40
		From Ap	ril 7, 2019	From Aug	ust 11, 2020
ŀ	Exercise period	To March 31, 2027		To August 9, 2028	
Cone	ditions on exercise	xercise (Note) 2		(Note) 2	
Status of	Directors (excluding external directors)	Number of subscription rights to shares Number of underlying shares Number of holders	40 units 200,000 shares 1 person	Number of subscription rights to shares Number of underlying shares Number of holders	57 units 285,000 shares 1 person
holding	External directors	_		-	_
by officers	Corporate auditors	Number of subscription rights to shares Number of underlying shares Number of holders	5 units 25,000 shares 1 person	_	_

Name o	of subscription rights to shares		rights to shares ound)		rights to shares ound)
Date	of resolution to issue	August	10, 2018	May 1	7, 2019
Number of subscription rights to shares (units)		80 (N	Tote) 1	28 (Note) 1	
Class an	d number of underlying	Commo	on stock	Common stock	
	shares (shares)	400,000	(Note) 1	140,000	(Note) 1
Cash payment for subscription rights to shares (yen per unit)		27,	300		)
Exercise price (yen per share)		228 255		55	
	г : : 1	From August 10, 2020		From May 18, 2021	
	Exercise period	To August 9, 2028		To May	16, 2029
Cor	nditions on exercise	(Note) 2		(Note) 2	
Status of holding by officers	Directors (excluding external directors)  External directors	Number of subscription rights to shares Number of underlying shares Number of holders	40 units 200,000 shares 1 person	Number of subscription rights to shares Number of underlying shares Number of holders	20 units 100,000 shares 1 person
	Corporate auditors	_		-	_

Name o	of subscription rights to shares	Subscription rights to shares (6 th round)		Subscription rights to shares (9 th round)	
Date	Date of resolution to issue May 17, 2019		April 13, 2020		
Number of subscription rights to shares (units)		33 (Note) 1		390 (Note) 3	
	d number of underlying	Commo	on stock	Common stock	
	shares (shares)	165,000	(Note) 1	195,000	(Note) 3
	nyment for subscription rights to shares (yen per unit)	36,	800	0	
	Exercise price (yen per share)	248		705	
	D ' ' 1	From May 17, 2021		From April 14, 2022	
	Exercise period	To May 16, 2029		To April 13, 2030	
Cor	nditions on exercise	(Note) 2		(Note) 2	
Status of holding by officers	Directors (excluding external directors)  External directors	Number of subscription rights to shares Number of underlying shares Number of holders	6 units 30,000 shares 1 person	Number of subscription rights to shares Number of underlying shares Number of holders Number of subscription rights to shares Number of underlying shares Number of underlying shares Number of holders	200 units 100,000 shares 1 person 50 units 25,000 shares 1 person
	Corporate auditors	_			

Name o	of subscription rights to shares	Subscription rights to shares (11 th round)		Subscription rights to shares (12 th round)	
Date	Date of resolution to issue March 23, 2021		23, 2021	May 12, 2022	
Number of subscription rights to shares (units)		638 (Note) 3		1,080 (Note) 4	
Class an	d number of underlying	Common stock		Common stock	
	shares (shares)	319,000	(Note) 3	108,000	(Note) 4
Cash payment for subscription rights to shares (yen per unit)		0 0		0	
	Exercise price (yen per share)	779		804	
	F ' ' 1	From March 24, 2023		From Ma	y 13, 2024
	Exercise period	To March 23, 2031		To May 12, 2032	
Cor	nditions on exercise	(Note) 2		(Note) 2	
Status of holding by officers	Directors (excluding external directors)  External directors	Number of subscription rights to shares Number of underlying shares Number of holders	100 units 50,000 shares 2 persons	Number of subscription rights to shares Number of underlying	
	Corporate auditors	_			

Name of subscription rights to shares		Subscription rights to shares (13 th round)	
Date of resolution to issue		May 12, 2022	
Number of subscription rights to shares (units)		200 (Note) 4	
Class an	d number of underlying	Common stock	
	shares	20,000	(Note) 4
Cash payment for subscription rights to shares (yen per unit)		9,2	200
Exercise price (yen per share)		780	
	Exercise period	From May 13, 2024 To May 12, 2032	
Cor	nditions on exercise	(Note) 2	
Status of holding by officers	Directors (excluding external directors)  External directors	Number of subscription rights to shares Number of underlying shares Number of holders	120 units 12,000 shares 1 person
	Corporate auditors	_	_

(Notes) 1. The number of underlying shares per unit of subscription rights to shares is 5,000 shares.

- 2. Conditions on exercise of subscription rights to shares
  - (a) Those to whom subscription rights to shares are allotted ("Holders of Subscription Rights to Shares") must continue to be directors or employees of the Company or its subsidiaries up to the date of exercise to be eligible, except when directors retire upon expiration of their term of office, employees retire at full retirement age, or there is any other due reason specifically provided by the Board of Directors.
  - (b) Subscription rights to shares may be inherited when Holders of Subscription Rights to Shares die.
  - (c) Subscription rights to shares less than one unit may not be exercised.
- 3. The number of underlying shares per unit of subscription rights to shares is 500 shares.
- 4. The number of underlying shares per unit of subscription rights to shares is 100 shares.

(2) Subscription rights to shares granted to the Company's employees, etc. as consideration for execution of duties during the fiscal year ended December 31, 2022

Name of subscription rights to shares		Subscription rights to shares (12 th round)	
Date of	resolution to issue	May 12, 2022	
Number of subscription rights to shares (units)		1,080 (Note) 1	
Class and n	umber of underlying	Common stock	
sha	ares (shares)	108,000	(Note) 1
Cash payment for subscription rights to shares (yen per unit)		(	)
Exercise price (yen per share)		804	
F	ii. 1	From May	y 13, 2024
EXC	ercise period	To May 12, 2032	
Condit	ions on exercise	(Note) 2	
Status of grant to employees, etc.	Employees of the Company	Number of subscription rights to shares Number of underlying shares Number of holders	800 units 80,000 shares 15 persons

- (Notes) 1. The number of underlying shares per unit of subscription rights to shares is 100 shares.
  - 2. Conditions on exercise of subscription rights to shares
    - (a) Those to whom subscription rights to shares are allotted ("Holders of Subscription Rights to Shares") must continue to be directors or employees of the Company or its subsidiaries up to the date of exercise to be eligible, except when directors retire upon expiration of their term of office, employees retire at full retirement age, or there is any other due reason specifically provided by the Board of Directors.
    - (b) Subscription rights to shares may be inherited when Holders of Subscription Rights to Shares die.
    - (c) Subscription rights to shares less than one unit may not be exercised.

(3) Other material matters regarding subscription rights to shares (as of December 31, 2022)

Name of subscription rights to shares	Subscription rights to shares (8 th round)	
Category and number of eligible person (person)	Joint researcher: 1	
Date of resolution to issue	August 7, 2019	
Number of subscription rights to shares (units)	730 (Note) 1	
Class and number of underlying	Common stock	
shares (shares)	365,000 (Note) 1	
Cash payment for subscription rights to shares (yen per unit)	0	
Exercise price (yen per share)	255	
	From August 7, 2020 or date of	
Exercise period	listing, whichever comes later	
	to August 6, 2029	
Conditions on exercise	(Note) 2	

(Notes) 1. The number of underlying shares per unit of subscription rights to shares is 500 shares.

- 2. Conditions on exercise of subscription rights to shares
  - (a) Those to whom subscription rights to shares are allotted ("Holders of Subscription Rights to Shares") must continue to be related parties of the Company or its subsidiaries up to the date of exercise to be eligible, except when directors retire upon expiration of their term of office, employees retire at full retirement age, or there is any other due reason specifically provided by the Board of Directors.
  - (b) Subscription rights to shares may be inherited when Holders of Subscription Rights to Shares die.
  - (c) Subscription rights to shares less than one unit may not be exercised.

#### 4. Officers

(1) Directors and corporate auditors (as of December 31, 2022)

Name	Post and responsibility	Material posts concurrently held
Koji Tamada	President & CEO,	Professor of Immunology, Yamaguchi University,
	Representative Director	Graduate School of Medicine
Tsutomu	Director,	
Tokashiki	Manager of Business Planning	_
	Research Dept.	
Hiroko Nagai	Director,	
	Manager of Administrative Dept.	_
Philippe	Director	External Director of Rezolute Inc.
Fauchet		External Director of LUCA Science Inc.
		External Director of JCR Pharmaceuticals Co., Ltd
Kazuyuki	Full-time Corporate Auditor	
Fujiwara		_
Hironari	Corporate Auditor	Partner of Vasco da Gama Law Offices (Attorney at
Hashioka		Law)
		External Corporate Auditor of Trenders, Inc.
		External Director of Kufu Company Inc.
Yukiyasu	Corporate Auditor	Representative of Nakata Yukiyasu Accounting &
Nakata		Tax Office
		Corporate Auditor of Promat Japan Corporation

(Notes) 1. Mr. Philippe Fauchet, Director, is external director.

- 2. Mr. Kazuyuki Fujiwara, Mr. Hironari Hashioka, and Mr. Yukiyasu Nakata, Corporate Auditors, are external corporate auditors.
- 3. Mr. Hironari Hashioka, Corporate Auditor, is an attorney at law, and Mr. Yukiyasu Nakata, Corporate Auditor, is a certified public accountant and tax accountant.
- 4. Upon conclusion of the 7th Annual General Meeting of Shareholders held on March 29, 2022, Mr. Hidenobu Ishizaki and Mr. Yoshinori Ito, Directors, retired due to expiration of their terms of office.
- 5. Mr. Shigeo Furusawa retired from office due to resignation on June 15, 2022.
- 6. Pursuant to provisions of Article 427, Paragraph 1 of the Companies Act, Mr. Hironari Hashioka and Mr. Yukiyasu Nakata, Corporate Auditors, and the Company entered into an agreement to limit the liability for damages provided for in Article 423, Paragraph 1 of the Companies Act of Japan. The maximum liability for damages under such contracts is limited to the amount stipulated by law.
- 7. As stipulated in Article 430-3, Paragraph 1 of the Companies Act, the Company has obtained a directors' and corporate auditors' liability insurance policy with an insurance company that covers all directors and corporate auditors of the Company. The insurance policy covers compensation for damages and litigation expenses that may arise from the performance of their duties, and the Company bears all insurance

## premiums.

(2) Directors and corporate auditors who retired during the fiscal year

As noted above, Mr. Hidenobu Ishizaki and Mr. Yoshinori Ito, Directors, and Mr. Shigeo Furusawa,

Corporate Auditor, retired.

## (3) Remuneration, etc. of directors and corporate auditors

①Policy on Determining Directors' and Auditors' Remuneration Amount or Calculation Method The Company's policy for determining the amount of remuneration and method of calculation for directors and auditors is described in the Company's Regulation of Executive Compensation.

The remuneration for directors is determined by the Board of Directors (or by the Representative Director if the Board of Directors entrusts the decision to the Representative Director) within the total amount of remuneration approved at the General Meeting of Shareholders in accordance with the Regulation of Executive Compensation. The determination takes into consideration various factors including the balance between remuneration, management details, and employee salaries, and is aligned with the standards of the industry.

The remuneration for corporate auditors is determined through discussions among the corporate auditors, based on the Regulation of Executive Compensation, within the total amount of remuneration approved at the General Meeting of Shareholders. The discussions take into consideration various factors including the balance among the remuneration, the content of audits, and employee salaries.

The Remuneration Committee reviewed and determined the remuneration amount for directors and corporate auditors for the most recent fiscal year. The General Meeting of Shareholders passed a resolution to approve the amount of remuneration, which was 150,000 thousand yen for directors (resolved at the Ordinary General Meeting of Shareholders held on March 24, 2020) and 50,000 thousand yen for corporate auditors (resolved at the Extraordinary General Meeting of Shareholders held on May 17, 2019). The amount of remuneration for each individual director is determined within the limit of the approved amount. The determination of each director's remuneration was entrusted to Koji Tamada, Representative Director, by the Board of Directors, based on the proposal of the Remuneration Committee. This is because it is appropriate to evaluate the level of contribution by those most familiar with the Company's business.

In principle, the Board of Directors is primarily responsible for deciding on the granting of stock options. However, the Compensation Committee may consider the matter in advance as necessary and appropriate.

②Total amount of remuneration by director classification and number of directors subject to remuneration

Post	Number	Total amount of remuneration, etc.
Directors	6	¥64 million
(of which, external directors)	(1)	(¥8 million)
Corporate auditors	4	¥12 million
(of which, external corporate	(4)	(¥12 million)

auditors)		
Total	10	¥77 million
(of which, external officers)	(5)	(¥20 million)

(4) Other material matters regarding officers

Not applicable.

- (5) External officers
  - (a) Relationship between the Company and other companies where our officers hold material concurrent positions

Not applicable.

(b) Family relationship with business executing persons of the Company or entities that have a special relationship with the Company

Not applicable.

# (c) Major activities during the fiscal year ended December 31, 2022

	Attendance and participation		
Philippe Fauchet	Mr. Fauchet attended all 17 meetings of the Board of Directors held		
Director	during the fiscal year ended December 31, 2022, and participated in		
Director	discussions, as necessary.		
Kazuyuki Fujiwara	Mr. Fujiwara attended all 17 meetings of the Board of Directors held		
Corporate Auditor	during the fiscal year ended December 31, 2022, and participated in		
Corporate Auditor	discussions, as necessary.		
	He also attended all 35 meetings of the Board of Corporate Auditors held		
	during the fiscal year ended December 31, 2022, and participated in		
	discussions, as necessary.		
Hironari Hashioka	Mr. Hashioka attended all 17 meetings of the Board of Directors held		
Corporate Auditor	during the fiscal year ended December 31, 2022, and participated in		
corporate riuditor	discussions, as necessary from the viewpoint of legal counsel.		
	He also attended all 35 meetings of the Board of Corporate Auditors held		
	during the fiscal year ended December 31, 2022, and participated in		
	discussions, as necessary.		
Shigeo Furusawa	Mr. Furusawa attended all 9 meetings of the Board of Directors held		
Corporate Auditor	during the fiscal year ended December 31, 2022 (during his term of		
P	office), and participated in discussions, as necessary.		
	He also attended all 19 meetings of the Board of Corporate Auditors held		
	during the fiscal year ended December 31, 2022 (during his term of		
	office), and participated in discussions, as necessary.		
Yukiyasu Nakata	Mr. Nakata attended all 17 meetings of the Board of Directors held		
Corporate Auditor	during the fiscal year ended December 31, 2022, and participated in		
1	discussions, as necessary from the viewpoint of CPA and tax accountant.		
	He also attended all 35 meetings of the Board of Corporate Auditors held		
during the fiscal year ended December 31, 2022, and 1			
discussions, as necessary.			

#### 5. Independent Auditors

(1) Name: Deloitte Touche Tohmatsu LLC

### (2) Remuneration of independent auditors

	Amount of remuneration
Amount of remuneration paid to the independent auditors for the	
fiscal year ended December 31, 2022	
a. Remuneration based on attestation service	¥37,620 thousand
b. Remuneration based on non-audit service	¥12,810 thousand
Total amount of cash and other remuneration to be paid by the Company to the independent auditors	¥50,430 thousand

#### (3) Description of non-audit services

During the fiscal year ended December 31, 2022, the Company engaged Deloitte Touche Tohmatsu LLC to obtain advice on the consideration of accounting policies in connection with the application of "Accounting Standard for Revenue Recognition" and to prepare a comfort letter in English for the overseas share issuance scheduled in Mach 2023.

## (4) Reason why the Board of Corporate Auditors agreed on the independent auditors' remuneration

In light of "Practical Guideline on Cooperation with Independent Auditors" issued by Japan Audit & Supervisory Board Members Association, the Board of Corporate Auditors agreed on the amount of remuneration paid to the independent auditors as provided for in Article 399, Paragraph 1 of the Companies Act, based on the verification and examination of the independent auditors' audit plan, the performance status of their duties in previous years, and the calculation basis for estimated remuneration by obtaining necessary documents from and conducting interviews with directors, relevant departments, and independent auditors.

#### (5) Policies to determine dismissal or non-reappointment of the independent auditors

When it is acknowledged that the independent auditors fall under any of the items in Article 340, Paragraph 1 of the Companies Act, the Board of Corporate Auditors will dismiss the independent auditors with the unanimous consent of all members of the Board of Corporate Auditors.

When it is determined that the independent auditors are incapable of adequately performing the audit service, or when determined necessary, the Board of Corporate Auditors will decide on the content of the agenda regarding dismissal or non-reappointment of the independent auditors to be submitted to a general meeting of shareholders.

#### 6. The Company's System and Policies

- (1) Summary of the systems to ensure that the execution of duties by directors and employees is in compliance with laws and regulations and the Articles of Incorporation and other systems to ensure proper business operation
  - a. System to ensure that the execution of duties by directors is in compliance with laws and regulations and the Articles of Incorporation
    - (a) The Board of Directors shall make decisions on important management affairs in accordance with laws and regulations, the Articles of Incorporation, resolutions of general meeting of shareholders and "Regulations of the Board of Directors."
    - (b) President & CEO shall make decisions on the Company's business execution delegated by directors in accordance with "Regulations of the Board of Directors" and execute duties in accordance with such decisions, resolutions of the Board of Directors meetings and "Regulations of the Board of Directors."
    - (c) The Board of Directors shall determine the basic policy of internal control and monitor whether directors appropriately design and operate internal control system and execute their duties in compliance with such system.
    - (d) Directors shall promote information sharing with other directors to mutually monitor business execution.
    - (e) Directors shall be audited based on the audit policy and plan developed by corporate auditors.
    - (f) The Administrative Department shall promote the use of the whistleblowing system according to "Whistleblowing Regulations" in an effort to detect violations of laws or issues that might inhibit "Core Value."
  - b. System to store and manage information on the directors' execution of the duties
    - Minutes of general meeting of shareholders and Board of Directors meetings and important information on management and business execution shall be appropriately recorded and maintained for a specified period in accordance with laws and regulations and relevant rules including "Approval Rules" and "Approval Procedural Regulations." Other relevant rules shall be reviewed and updated, as necessary.
  - c. System to ensure efficient execution of duties by directors
    - (a) To ensure efficient execution of duties by directors, provisions regarding operation of the Board of Directors meetings shall be established in "Regulations of the Board of Directors" and the Board of Directors meetings shall be held on a monthly basis and as necessary.
    - (b) Directors shall endeavor to promptly obtain accurate management information
  - d. System to ensure that the execution of duties by employees is in compliance with laws and regulations and the Articles of Incorporation

President & CEO shall establish a system whereby any compliance-related incident will be reported to President & CEO, the Board of Directors, corporate auditors, and corporate lawyers.

- e. Regulations and other systems to manage potential risks of losses
  - (a) President & CEO shall establish a system to minimize risks by identifying and assessing company-wide risks and prepare countermeasures in coordination with directors in charge and department managers.
  - (b) To facilitate risk management, the Company shall establish risk management rules and other internal rules to raise awareness of risks, enable early detection and prevention, and determine emergency procedures.
- f. Matters concerning employees assigned to assist duties of corporate auditors when such assignment is requested by corporate auditors

Although the Company does not assign any employees to assist duties of corporate auditors, the Board of Directors may appoint and assign such employees based on discussions with corporate auditors when necessary.

g. Matters concerning independence of employees assigned to assist duties of corporate auditors from directors when such assignment is requested by corporate auditors

During the assignment, the right of command over the assigned employees shall be considered to be transferred to corporate auditors, and therefore the assigned employees shall not be subjected to instruction from directors.

- h. System for directors and employees to report to corporate auditors and other systems concerning reports to corporate auditors
  - (a) Corporate auditors shall attend the Board of Directors meetings as well as management meetings and other important meetings concerning business execution such as budget meetings to receive reports on material issues of the Company, facts that may cause damages to the Company, etc.
  - (b) Directors and employees shall report to corporate auditors about important matters to be discussed and important decisions made by the Board of Directors, decisions made at other important meetings, significant accounting policies and standards and changes thereof, and other important matters that need to be reported.
  - (c) Directors and employees shall immediately report to corporate auditors when they become aware of any facts that may cause substantial damages to the Company, fraudulent acts, or serious violation of laws and regulations or the Articles of Incorporation.
- i. Other systems to ensure effective performance of audit by corporate auditors
  - (a) Corporate auditors shall hold meetings with President & CEO on a regular basis to communicate and exchange opinions.
  - (b) Corporate auditors shall also exchange opinions and information with independent auditors to maintain coordination and request investigation and report, as necessary.
- j. Basic policy and system to eliminate anti-social forces

The basic policy of the Company shall be not to have any relationship with any anti-social forces,

organizations, or individuals and not to respond to any unreasonable or illegal demands. Directors and employees shall be thoroughly informed about such policy, and the Company shall establish a system enabling the entire company to promptly take actions by collecting information from relevant administrative agencies on a regular basis and maintaining close contact with relevant administrative agencies and legal experts in the event of an incident.

### (2) Summary of the operating status of the systems to ensure proper business operation

In accordance with the aforementioned basic policy to ensure proper business operation, the Company has established systems to ensure proper business operation as a company and implemented the following measures to ensure proper operation of such systems.

- (a) The Board of Directors consists of four directors (including one external director) and makes decisions about important matters concerning the Company's business operation and matters provided for by laws and regulations. In principle, the Board of Directors meetings are held on a monthly basis and also when needed. During the fiscal year ended December 31, 2022, the Board of Directors meetings were held 17 times, where, in accordance with "Regulations of the Board of Directors," directors deliberated and decided on items on agenda, monitored the status of execution of duties, and actively exchanged opinions, enabling prompt decision making and ensuring effective monitoring.
- (b) Compliance trainings are held annually to thoroughly inform employees of "Compliance Rules," etc.
- (c) Internal auditors perform internal audit on a regular basis to verify that the Company's business operation is in compliance with laws and regulations, the Articles of Incorporation, internal rules, etc. The results of the internal audit along with areas for improvement are reported to President & CEO and corporate auditors. Corporate auditors meet with independent auditors and internal auditors, as needed, to exchange opinions about compliance, the status of the internal control system in place, etc.
- (d) The Company has a system in place to eliminate anti-social forces in accordance with "Anti-social Forces Elimination Rules," with Representative Director as the responsible person and the Administrative Department as the responsible division. The Company also coordinates with external agencies in an effort to eliminate anti-social forces, and receives instructions and collects information.

# The 8th Fiscal Year

Supplementary Schedules
Related to Business Report

Noile-Immune Biotech, Inc.

2-12-10 Shiba-Daimon, Minato-ku, Tokyo

# **Supplementary Schedules**

(From January 1, 2022 to December 31, 2022)

 Other significant matter to supplement the contents of the Business Report Not applicable. The 8th Fiscal Year

**Financial Statements** 

Noile-Immune Biotech, Inc.

2-12-10 Shiba-Daimon, Minato-ku, Tokyo

# Balance Sheet

(As of December 31, 2022)

(In thousands of yen)

Account	Amount	Account	Amount
(Assets)		(Liabilities)	
Current assets	4,584,184	Current liabilities	335,181
Cash and deposits	4,520,997	Other payables	217,815
Inventory	3,926	Accrued expenses	45,939
Advance payments	26,943	Income taxes payable	18,309
Prepaid expenses	27,015	Contract liabilities	4,846
Other	5,301	Deposits received	44,728
Fixed assets	56,848	Other	3,542
Investments and other assets	56,848	Non-current liabilities	5,233
Long-term prepaid expenses	3,007	Asset retirement obligations	5,233
Long-term deposits	35,034	Total liabilities	340,414
Guarantee deposits	18,806	(Net assets)	
		Shareholders' equity	4,293,716
		Capital	2,787,552
		Capital surplus	2,765,396
		Capital reserve	2,765,396
		Retained earnings	(1,259,232)
		Other retained earnings	(1,259,232)
		Retained earnings brought forward	(1,259,232)
		Subscription rights to shares	6,901
		Total net assets	4,300,617
Total assets	4,641,032	Total liabilities and net assets	4,641,032

(Note) Amounts less than one thousand yen is rounded down.

# Statement of Income

(From January 1, 2022 to December 31, 2022)

(In thousands of yen)

Account	Amour	nt
Operating revenue		625,783
Operating expenses		
Operating cost	7,077	
Research and development expenses	334,804	
Other selling, general and administrative expenses	390,247	732,129
Operating loss		(106,345)
Non-operating income		
Interest income	41	
Interest on refund	14	
Subsidy income	330	
Foreign exchange gain	5,477	5,863
Non-operating expenses		
Listing expenses	268,210	
Outsourcing expense	13,758	
Share issuance cost	1,750	
Other	2	283,720
Ordinary loss		(384,202)
Net loss before income taxes		(384,202)
Income taxes - current	2,420	2,420
Net loss		(386,622)

(Note) Amounts less than one thousand yen is rounded down.

# Statement of Changes in Net Assets

(From January 1, 2022 to December 31, 2022)

(In thousands of yen)

	Shareholders' equity					
	Capital	Capital surplus	Retained earnings	Total shareholders' equity	Subscription rights to shares	Total net assets
		Capital reserve	Retained earnings brought forward			
Beginning balance	2,537,519	2,515,363	(872,610)	4,180,272	5,061	4,185,334
Changes during the year						
Issuance of new shares	250,033	250,033		500,066		500,066
Net loss			(386,622)	(386,622)		(386,622)
Issuance of subscription rights to shares					1,840	1,840
Net changes in items other than shareholders' equity during the year						
Total changes during the year	250,033	250,033	(386,622)	113,443	1,840	115,283
Ending balance	2,787,552	2,765,396	(1,259,232)	4,293,716	6,901	4,300,617

(Note) Amounts less than one thousand yen is rounded down.

### [Notes to financial statements]

(Significant accounting policies)

# 1. Valuation basis and method of inventory

- (1) Work in process: Stated at cost using the specific identification method (Net book value is written down to reflect a decline in profitability)
- (2) Supplies: Stated at cost using the last purchase cost method.

## 2. Translation of assets and liabilities denominated in foreign currencies to Japanese yen

Monetary receivables and payables denominated in foreign currencies are translated into Japanese yen using the spot exchange rates at the end of the reporting period, with the difference arising from the translation recognized in profit or loss.

## 3. Recognition criteria for allowance

To provide for credit loss on trade receivables, loans receivable, etc., allowance for doubtful accounts is recorded at the estimated uncollectible amount based on the past bad debt ratio for performing receivables and based on individual assessment of collectability for non-performing receivables.

No allowance for doubtful accounts is recorded for the fiscal year ended December 31, 2022 as there was no credit loss recognized or non-performing receivables.

# 4. Recognition criteria for major revenue and expenses

The description of major performance obligations related to revenue from contracts with customers in our principal business and the point at which these performance obligations are generally satisfied are as follows.

### • Licensing revenue

The Company recognizes income generated from granting licenses for intellectual property acquired through research and development (upfront fee, milestone income, etc.) as revenue.

In general, income generated from granting a license is recognized as revenue over the licensing term if the nature of the arrangement is determined as provision of a right to access the Company's intellectual property which is a performance obligation satisfied over time, and recognized as revenue at the point when the license is granted if the nature is determined as provision of a right to use the Company's intellectual property which is a performance obligation satisfied at a point in time.

Milestone income is recognized as revenue from the point when all conditions are satisfied as uncertainties regarding revenue recognition are not resolved and the amount of recognized revenue may be reduced until conditions set forth in the agreement, such as progress of the research and

development, are satisfied.

Transaction price to be recognized as revenue is based on the amount specified in the agreement in consideration of the amount allocated to other performance obligations included in the agreement.

Consideration for transactions are payable from customers within one year after the conclusion of the agreement, achievement of certain milestones, etc. No significant financing component is included in the agreements.

(Accounting estimates)

Recoverability of deferred tax assets

(1) Amounts recognized in the financial statements for the fiscal year ended December 31, 2022

Deferred tax assets:  $\Psi$ — thousand

(2) Information on significant accounting estimates related to identified items

Deferred tax assets are calculated based on the company classification specified in the "Implementation Guidance on Recoverability of Deferred Tax Assets" (Accounting Standards Board of Japan (ASBJ) Guidance No. 26) for deductible temporary differences and unused tax losses by reasonably estimating taxable profits in future years and assessing the recoverability. The amount of taxable profits is estimated based on the budgets, etc. for the following fiscal year approved by the Board of Directors.

The estimate of taxable profits and the assessment of recoverability of deferred tax assets have been made under the assumption that the impact of COVID-19 on the Company's business results is limited. However, because there is high uncertainty about the impact of the infection, the estimate of taxable profits and the calculated amount of deferred tax assets for the fiscal year ended December 31, 2022 may change depending on the situation of COVID-19 infections in the future.

(Changes in accounting policy)

For the fiscal year ended December 31, 2022

(Application of accounting standard for revenue recognition, etc.)

The Company applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020, "Accounting Standard for Revenue Recognition"), etc. from January 1, 2022, and recognizes revenue at an amount that it expects to receive in exchange for the promised goods or services when the control of the goods or services is transferred to a customer.

We applied the Accounting Standard for Revenue Recognition, etc. from January 1, 2022 pursuant to the transitional treatment provided for in the proviso of Paragraph 84 of the Accounting Standard for Revenue Recognition, with the cumulative effect of the retrospective application, assuming the new accounting policy had been applied to periods prior to January 1, 2022, adjusted to the beginning balance

6

of retained earnings as of January 1, 2022.

There was no impact of the application of the Accounting Standard for Revenue Recognition, etc. on profit or loss for the fiscal year ended December 31, 2022 and retained earnings as of January 1, 2022.

(Application of accounting standard for fair value measurement, etc.)

The Company applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019, "Accounting Standard for Fair Value Measurement"), etc. from January 1, 2022, and the new accounting policies stipulated in the Accounting Standard for Fair Value Measurement, etc. are applied prospectively pursuant to the transitional treatment provided for in Paragraph 19 of the Accounting Standard for Fair Value Measurement and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019). The application has no impact on the financial statements.

# (Statement of changes in net assets)

1. Class and total number of shares issued and outstanding as of December 31, 2022

### Common stock

Balance as of January 1, 2022	38,958,665 shares
Increase during the year	621,200 shares
Decrease during the year	- shares
Balance as of December 31, 2022	39,579,865 shares

(Reason of change)

Increase due to issuance of new shares through a third-party allotment: 621,200 shares

# 2. Subscription rights to shares

The class and number of shares to be issued upon exercise of subscription rights to shares as of December 31, 2022 (excluding those whose exercise period has yet to start)

Subscription rights to shares	Class of underlying shares	Number of underlying shares	Outstanding balance
2nd round	Common stock	615,000 shares	123 units
3rd round	Common stock	205,000 shares	41 units
4th round	Common stock	240,000 shares	48 units
5th round	Common stock	45,000 shares	9 units
6th round	Common stock	60,000 shares	12 units
9th round	Common stock	39,000 shares	78 units
10th round	Common stock	3,000 shares	6 units

# (Deferred tax accounting)

Major components of deferred tax assets and liabilities

	(In thousands of yen)
Deferred tax assets	
Excess depreciation	5,424
One-time depreciation asset	17
Contract liabilities	473
Asset retirement obligations	1,602
Tax loss carryforward	590,248
Deferred tax assets subtotal	597,766
Valuation allowance for tax loss carryforward	(590,248)
Valuation allowance for total deductible temporary differences	(7,518)
Valuation allowance subtotal	(597,766)
Total deferred tax assets	0
Deferred tax liabilities	
Tangible fixed assets	0
Total deferred tax liabilities	0
Net deferred tax assets	

# (Financial instruments)

1 Overview of financial instruments

# (1) Policy on financial instruments

The Company limits its investment options to short-term deposits only and raises funds through equity financing.

# (2) Description and risk of financial instruments

Accounts receivable is trade receivable and exposed to credit risk of customers. Trade receivable denominated in foreign currencies is exposed to foreign exchange rate risk.

Other payables are trade payable and generally due within one year. Trade payable denominated in foreign currencies is exposed to foreign exchange rate risk.

# (3) Risk management system for financial instruments

(a) Management of credit risk (risk of default by customers, etc.)

For trade receivable, the Administrative Department manages due dates and outstanding balance for each customer in accordance with the sales management regulation and strives to detect possible uncollectible accounts due to deterioration of customers' financial condition at an early stage and mitigate loss.

- (b) Management of market risk (risk of changes in exchange rates, interest rates, etc.)
  - For trade receivable and payable denominated in foreign currencies, the Administrative Department monitors foreign exchange rates on a monthly basis.
- (c) Management of liquidity risk associated with funding (risk of being unable to make payments when due)

The Administrative Department manages liquidity risk by preparing and updating the cash flow plan in a timely manner based on the reports from relevant departments and maintaining liquidity on hand.

## (4) Supplemental information on fair value of financial instruments, etc.

The fair value of financial instruments includes values based on the market price or reasonably calculated values when there are no market prices. As such values are calculated using variable factors, using different assumptions may result in different values.

# (5) Concentration of credit risk

The Company's trade receivable is highly likely to concentrate on certain large customers.

# 2 Fair value of financial instruments

The disclosure on cash and deposits, other payables, income taxes payable and deposits received are omitted as they are settled within a short period of time and their carrying amounts approximates their fair values.

(Note) 1. The redemption schedule of monetary receivables after the reporting date For the fiscal year ended December 31, 2022

(In thousands of yen)

	Within one year	After one year through five years	After five years through 10 years	After 10 years
Cash and deposits	4,520,997	_	_	_
Total	4,520,997	_	_	_

(Related party transactions)

Not applicable

(Revenue recognition)

(1) Disaggregation of revenue from contracts with customers

(By type of goods or services)

(In thousands of yen)

Item	Fiscal year ended December 31, 2022
Revenue recognized at a point in time	597,147
Revenue recognized over time	28,635
Royalty	_
Revenue from contracts with customers	625,783
Other revenue	_
Revenue from external customers	625,783

- (2) Information that serves as the basis for understanding revenue from contracts with customers

  Please see "(Significant accounting policies) 4. Recognition criteria for major revenue and expenses."
- (3) Information on when and how much revenue is expected to be recognized in the future periods from the contracts with customers existing as of December 31, 2022
  - (a) Balance of contract liabilities, etc.

(In thousands of yen)

	Year ended December 31, 2022
Contract liabilities (Beginning balance)	6,020
Contract liabilities (Ending balance)	4,846

(b) Transaction price allocated to remaining performance obligations

The disclosure on transaction price allocated to remaining performance obligations is omitted as we have no significant transactions with an original expected duration exceeding one year.

(Per share information)

Net assets per share: ¥108.48 Net loss per share: ¥9.87

(Material subsequent events)

Not applicable

# The 8th Fiscal Year

Supplementary Schedules
Related to Financial Statements

Noile-Immune Biotech, Inc.

2-12-10 Shiba-Daimon, Minato-ku, Tokyo

# **Supplementary Schedules**

(From January 1, 2022 to December 31, 2022)

# 1. Details of tangible and intangible fixed assets

(In thousands of yen)

Category	Asset type	Carrying amount as of January 1	Increase during the year	Decrease during the year	Depreciation	Carrying amount as of December 31	Accumulated depreciation
Tangible fixed assets	Leasehold improvements						14,430
	Tool, furniture and fixtures		-	-	_	_	39,316
	Other		ı	ı	_	ı	585
	Total				_		54,332
Intangible	Software	_	_	_	_	_	2,711
fixed assets	Total	_	_	_	_	_	2,711

(Note) Accumulated depreciation includes accumulated impairment losses.

# 2. Details of research and development expenses

(In thousands of yen)

Account	Amount	Remarks
Salaries	51,252	
Bonus	1,395	
Legal welfare expense	7,781	
Recruitment and education expenses	3,529	
Travel and transportation expenses	6,268	
Repair expense	1,692	
Compensation	8,613	
Outsourcing expense	533	
Staffing expense	19,998	
Rent expense	9,827	
Research materials expense	3,867	
Research outsourcing expense	217,433	
Other	2,611	
Total	334,804	

# 3. Details of other selling, general and administrative expenses

(In thousands of yen)

Account	Amount	Remarks
Directors' remuneration	75,014	
Salaries	80,483	
Bonus	1,937	
Legal welfare expense	16,492	
Recruitment and education expenses	9,136	
Travel and transportation expenses	8,155	
Communication expense	2,286	
Office supplies expense	2,934	
Repair expense	640	
Membership fee	700	
Fees and commissions	7,229	
Compensation	43,968	
Outsourcing expense	26,578	
Staffing expense	4,983	
Rent expense	17,047	
Lease expense	2,171	
Insurance premium	1,905	
Taxes and dues	29,648	
Patent-related expense	55,266	
Other	3,666	
Total	390,247	

### INDEPENDENT AUDITOR'S REPORT

February 10, 2023

To the Board of Directors of Noile-Immune Biotech, Inc.:

Deloitte Touche Tohmatsu LLC Tokyo office

Designated Partner Engagement Partner	Certified Public Accountant	Hideki Ono
Designated Partner Engagement Partner	Certified Public Accountant	Akihiro Sano

# **Opinion**

Pursuant to Article 436, Paragraph 2, Item 1 of the Companies Act, we have audited the financial statements of Noile-Immune Biotech, Inc. (the "Company"), namely, the balance sheet as of December 31, 2022, and the statements of income and changes in net assets for the 8th fiscal year from January 1, 2022 to December 31, 2022, and the related notes and the accompanying supplementary schedules (the "Financial Statements, etc."). In our opinion, the Financial Statements, etc. referred to above present fairly, in all material respects, the

In our opinion, the Financial Statements, etc. referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and its financial performance for the year then ended in accordance with accounting principles generally accepted in Japan.

#### **Basis for Opinion**

We conducted our audit in accordance with auditing standards generally accepted in Japan. Our responsibilities under those standards are further described in the "Auditor's Responsibilities for the Audit of the Financial Statements, etc." section of our report. We are independent of the Company in accordance with the provisions of the Code of Professional Ethics in Japan, and we have fulfilled our other ethical responsibilities as auditors. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Other information

Other information comprises the business report and the accompanying supplementary schedules. Management is responsible for preparation and disclosure of the other information. Corporate Auditors and the Board of Corporate Auditors are responsible for supervising the execution of duties by directors with regard to design and operation of reporting process of the other information.

Our audit opinion on the financial statements does not cover the other information, and we do not express an opinion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

# Responsibilities of Management and Corporate Auditors and the Board of Corporate Auditors for the Financial Statements, etc.

Management is responsible for the preparation and fair presentation of the Financial Statements, etc. in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation and fair presentation of the Financial Statements, etc. that are free from material misstatement, whether due to fraud or error.

In preparing the Financial Statements, etc., management is responsible for assessing whether it is appropriate to prepare the Financial Statements, etc. based on the premise of a going concern and for disclosing matters related to going concern when it is required to do so in accordance with accounting principles generally accepted in Japan.

Corporate Auditors and the Board of Corporate Auditors are responsible for overseeing the Directors' execution of duties relating to the design and operation of the Company's financial reporting process.

# Auditor's Responsibilities for the Audit of the Financial Statements, etc.

Our responsibility is to obtain reasonable assurance about whether the Financial Statements, etc. as a whole are free from material misstatement, whether due to fraud or error, and to express an opinion on the Financial Statements, etc. from an independent standpoint in an auditor's report. Misstatements can arise from fraud or error and are considered material if they could reasonably be expected to, individually or collectively, influence the decisions of users taken on the basis of the Financial Statements, etc.

As part of an audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement, whether due to fraud or error, and design and perform audit procedures to address those risks. We select and apply audit procedures based on our judgement. In addition, we obtain sufficient and appropriate audit evidence to provide a basis for our opinion.
- Consider internal control relevant to the audit when performing risk assessment procedures in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies adopted by management and the method of their application as well as the reasonableness of accounting estimates made by management and the adequacy of related disclosures.
- Determine whether it is appropriate for management to prepare the Financial Statements, etc. on the premise of a going concern and, based on the audit evidence obtained, determine whether there exists a material uncertainty related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the Financial Statements, etc., or, if the disclosures in the Financial Statements, etc. pertaining to the material uncertainty are inadequate, we are required to issue a modified opinion. While our conclusions are based on the audit evidence obtained up to the date of our auditor's report, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate whether the presentation and disclosures of the Financial Statements, etc. are in accordance with accounting principles generally accepted in Japan, and whether the overall presentation, structure and content of the Financial Statements, etc. including related disclosures as well as the Financial Statements, etc. fairly represent the underlying transactions and accounting events.

We communicate with Corporate Auditors and the Board of Corporate Auditors regarding the planned scope and timing of the audit and material audit findings, including any significant deficiencies in internal control identified during the course of our audit, and other matters required under the auditing standards.

We also provide Corporate Auditors and the Board of Corporate Auditors with a statement that we have complied with professional ethical provision regarding independence in Japan, and communicate with them regarding matters that are reasonably considered to have an impact on our independence and any safeguards in place to reduce or eliminate obstacles, where applicable.

# Interest

Our firm or its designated engagement partners do not have any interest in the Company which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

### AUDIT REPORT

We, the Board of Corporate Auditors, have prepared this audit report upon deliberation based on the audit reports prepared by each Corporate Auditor concerning the performance of duties by Directors during the 8th fiscal year from January 1, 2022 to December 31, 2022, and hereby report as follows.

### 1. Methods and Details of the Audit by Corporate Auditors and the Board of Corporate Auditors

- (1) The Board of Corporate Auditors established the audit policies, the division of duties and other matters, and received reports from each Corporate Auditor on the status and results of its audits. In addition, the Board of Corporate Auditors received reports from Directors, etc., and the Independent Auditor regarding the performance of their duties, and requested explanations, as necessary.
- (2) In accordance with the standards for the audit by Corporate Auditors as established by the Board of Corporate Auditors, and based on the audit policies and division of duties, each Corporate Auditor communicated with Directors, the Internal Audit Department, employees, etc., using means such as telephone lines or the Internet, strived to gather information and enhance the audit environment, and also performed audit by the method described below.
  - (a) Each Corporate Auditor attended the meetings of the Board of Directors and other important meetings, received reports from Directors, employees and others regarding the performance of their duties, requested explanations as necessary, inspected important documents supporting decisions and other records and examined the status of operations and assets at the head office and major operating locations.
  - (b) In terms of the contents of the Board of Directors' resolutions concerning the establishment of systems, which are described in the Business Report, to ensure that Directors' performance of their duties is in compliance with the laws and regulations and the Company's Articles of Incorporation as stipulated in Article 100, Paragraphs 1 and 3 of the Ordinance for Enforcement of the Companies Act and the status of the systems established based on such resolution (internal control system), each Corporate Auditor periodically received reports from Directors, employees and others on the status of development and operation, requested explanations as necessary and expressed their opinion.
  - (c) Each Corporate Auditor monitored and verified whether the Independent Auditor maintained independence and performed proper audit, received reports from the Independent Auditor regarding the status of the performance of its duties, and requested explanations as necessary. Corporate Auditors also received the notification from the Independent Auditor that it had established a "system to ensure appropriate performance of its duties" (matters prescribed in each item of Article 131 of the Regulation on Corporate Accounting) in accordance with the "Quality Control Standards for Auditing" (Business Accounting Council, October 28, 2005), and requested explanation as necessary.

Based on the aforementioned methods, the Board of Corporate Auditors examined the business report and supplementary schedules thereto and the financial statements (balance sheet, statements of income and changes in net assets, and notes to the financial statements) and supplementary schedules thereto for the fiscal year ended December 31, 2022.

### 2. Results of Audit

- (1) Results of Audit of the Business Reports, etc.
  - (a) In our opinion, the business report and the supplementary schedules present fairly the condition of the Company in accordance with laws and regulations and the Articles of Incorporation of the Company.
  - (b) There are no fraudulent acts or serious violation of any applicable laws and regulations or the Articles of Incorporation of the Company concerning Directors' performance of their duties.
  - (c) In our opinion, the details of the Board of Directors' resolutions concerning the internal control system are appropriate. Furthermore, there were no findings to be reported regarding the description in the business report and Directors' performance of their duties concerning the internal control system.
- (2) Results of Audit of the Financial Statements and the Supplementary Schedules In our opinion, the auditing method and results of the Independent Auditor, Deloitte Touche Tohmatsu LLC, are appropriate.

March 2, 2023

# Board of Corporate Auditors of Noile-Immune Biotech, Inc.

Kazuyuki Fujiwara Full-time Corporate Auditor (External Corporate Auditor)

Hironari Hashioka External Corporate Auditor

Yasuyuki Nakata External Corporate Auditor