UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): October 29, 2024

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38650**	**47-4619612**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

230 Park Avenue
Suite 3350
New York, New York 10169
(Address of principal executive offices) (Zip Code)

(646) 885-8505
(Registrant's telephone number, include area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	YMAB	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On October 29, 2024, Y-mAbs Therapeutics, Inc., (the "**Company**") entered into a license agreement (the "**License Agreement**") with Nobelpharma Co., Ltd. ("**Nobel**"), effective October 23, 2024, pursuant to which the Company granted Nobel an exclusive license to develop and commercialize DANYELZA® (naxitamab-gqgk) or other formulations of naxitamab (the "**Licensed Product**") for the treatment of patients with neuroblastoma and, potentially, relapsed osteosarcoma in Japan (the "**Territory**").

The Company also agreed to license certain patents, and know-how related to the Licensed Product, including data and results and the Company's regulatory materials and strategies, to the extent necessary in connection with Nobel's efforts to obtain regulatory approval for and commercialize the Licensed Product in the Territory.

Nobel has agreed to use its commercially reasonable efforts to carry out development of the Licensed Product necessary to obtain regulatory approval for the Licensed Product in the Territory. The Company has agreed to bear 50% of certain development costs spent by Nobel for a specified Phase 1 study required for the development of the Licensed Product.

In connection with the execution of the License Agreement, Nobel will make an upfront cash payment to the Company of $2.0 million. Nobel is obligated to make additional payments of up to $31.0 million to the Company based on achievement of specified product milestones and commercial milestones relating to the Licensed Product. Nobel is also required to make low double-digit royalty payments on net sales of the Licensed Product in the Territory.

The License Agreement continues in force until terminated by either party, or until the later of (i) the expiration of the licensed patents, (ii) the date after which a biosimilar has garnered more than a specified percentage of the market, or (iii) 10 years after the product is first launched. Each party may terminate the License Agreement if the other party materially breaches the License Agreement and does not cure such breach within a specified period or if a party experiences certain insolvency events. In addition, Nobel may terminate the License Agreement in the event any safety issues arise with respect to Naxitamab and/or it is not economically or commercially reasonably to develop or commercialize the Licensed Product in the Territory.

The License Agreement contains representations, warranties, covenants, and indemnification provisions, subject to certain limitations.

The foregoing description of the License Agreement is not complete and is qualified in its entirety by reference to the text of the License Agreement, a copy of which is attached to this Current Report on Form 8-K ("**Form 8-K**") as Exhibit 10.1 and incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On November 4, 2024, the Company issued a press release with respect to the License Agreement described in Item 1.01 of this Form 8-K. A copy of the Company's press release is furnished as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

The information furnished pursuant to Item 7.01 of this Form 8-K, including Exhibit 99.1 furnished herewith, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1+	License Agreement, entered into on October 29, 2024 and effective October 23, 2024, by and between Y-mAbs Therapeutics, Inc. and Nobelpharma Co., Ltd.
99.1	Press Release dated November 4, 2024
104	Interactive Data File (embedded within the Inline XBRL document).

+ Portions of this exhibit have been omitted because the information omitted is both not material and the type that the Company treats as private or confidential.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Y-MABS THERAPEUTICS, INC.

Date: November 4, 2024

By: /s/ Michael Rossi
Michael Rossi
President and Chief Executive Officer

Certain information (marked as [***]) has been excluded from this exhibit because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is made and entered into as of October 23, 2024 (the "**Effective Date**") by and between:

Y-mAbs Therapeutics, Inc. ("**Licensor**"), a corporation incorporated and existing under the laws of Delaware, with its registered principal place of business at 230 Park Avenue, Suite 3350, New York, NY 10169, USA; and

Nobelpharma Co., Ltd. ("**Licensee**"), a corporation incorporated and existing under the laws of Japan, with its registered principal place of business at NMF Kayabacho Building, 1-17-24, Shinkawa, Chuo-ku, Tokyo 104-0033, Japan.

Licensor and Licensee are hereinafter collectively referred to as the "**Parties**" and individually as a "**Party**."

RECITALS

Whereas, Licensor is currently developing the product candidate using the Compound (as defined below) which target tumors that express GD2;

Whereas, Licensor has been granted world-wide rights to develop, market and commercialize the Compound as described in that certain License Agreement between Memorial Sloane Kettering Cancer Center ("MSK") and Licensor as of August 15, 2015;

Whereas, Licensor is the owner of the beneficial rights in and to the intellectual property rights relating to the Compound; and

Whereas, Licensee has expressed its interest in receiving a sub-license of such intellectual property rights from Licensor to engage in the development and commercialization of the Compound and the Licensed Product (as defined below).

Now, therefore, for and in consideration of the premises and covenants contained herein, the Parties hereby agree as follows:

Article 1 Definitions

1.1 For the purpose of this Agreement, the following capitalized terms (the singular may include the plural and vice versa) shall have the meaning respectively in this Article.

(1) "**Affiliate**" means any corporation or other business entity controlling, controlled by, or under common control with any party; and for such purpose control means direct or indirect ownership of more than fifty percent (50%) of the voting interest in such corporation or other business entity.

(2) "**Business Day**" means a day other than Saturday, Sunday or any day on which the Bank of Japan or commercial banks located in New York, New York are authorized or obligated by applicable Laws to close.

(3) "**Calendar Quarter**" means each respective period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

(4) "**Calendar Year**" means each respective period of twelve (12) consecutive calendar months ending on December 31.

(5) "**Commercialization**", "**Commercialize**" or "**Commercializing**" means any and all activities conducted to commercialize the Licensed Product or other pharmaceutical products, including, without limitation, manufacturing for sale, having made, importing, exporting, marketing, packaging, promoting, distributing, offering for sale, selling, and consigning for sale of the Licensed Product or other pharmaceutical products and all attendant medical affairs activities.

(6) "**Commercial Milestone Event**" has the meaning ascribed to it in Section 6.3.

(7) "**Commercially Reasonable**", or "**Commercially Reasonable Efforts**" means, with respect to a Party (directly or through Affiliates or sublicensees) performing activities under this Agreement, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances, but no less than the efforts and resources commensurate with those efforts commonly used in the biopharmaceutical industry by a company of comparable size in connection with the development, manufacture or commercialization of biopharmaceutical products of similar market potential at a similar stage of development or commercialization in its product lifecycle, but, with respect to Licensee's obligations under this Agreement, not taking into account any competitive product researched, developed or commercialized by Licensee or in which Licensee will share profits or revenues from the sale thereof. Commercially Reasonable Efforts requires, with respect to an obligation under this Agreement, that a Party reasonably and in good faith: (i) set and seek to achieve reasonable objectives for carrying out such obligation and (ii) reasonably make and implement decisions and allocate resources designed to advance progress with respect to such objectives, all taking into account the factors referred to above.

(8) "**Compound**" means Naxitamab.

(9) "**Confidential Information**" has the meanings ascribed to it in Article 14.

(10) "**Development**", "**Develop**" or "**Developing**" means any and all studies, test, research, development or other activities necessary or useful to seek, obtain and maintain the Regulatory Approval for the Licensed Product, including, but not limited to, non-clinical studies, clinical trials and safety tests of the Licensed Product or other pharmaceutical products, filing an NDA for the Licensed Product, and negotiation with the Regulatory Authority for the registration of the Licensed Product in the Territory.

(11) "**Development Plan**" has the meaning ascribed to it in Section 3.3.

(12) "**Indication**" means neuroblastoma ("**NB**") and an option of Osteosarcoma ("**OS**").

(13) "**Infringement Notice**" has the meaning ascribed to it in Section 11.3.

(14) "**JSC**" has the meaning ascribed to it in Section 4.1.

(15) "**Launch**" means the first commercial sale of a Licensed Product to a Third Party in the Territory by Licensee or any of their respective Affiliates after the Regulatory Approval has been obtained for such Licensed Product.

(16) "**Law**" shall mean any law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, guidance, directive, permit (including any Regulatory Approval), or other requirement of any governmental authorities including any regulatory authorities.

(17) "**Licensed Patents**" mean, any Licensor Patents in the Territory as of the Effective Date or at any time during the Term, that covers the Compound or Licensed Products including those listed in Exhibit A that, in the absence of the right thereunder, would be infringed by the activities by Licensee under this Agreement.

(18) "**Licensed Product**" means any pharmaceutical formulations using the Compound as an active pharmaceutical ingredient for the Indication.

(19) "**Licensee Indemnitees**" has the meaning ascribed to it in Section 18.2.

(20) "**Licensee's Intellectual Property**" has the meaning ascribed to it in Section 13.2.

(21) "**Licensor Indemnitees**" has the meaning ascribed to it in Section 18.1.

(22) "**Licensor Know How**" means all tangible and intangible techniques, technology, practices, trade secrets, inventions (whether patentable or not), processes, formulations, media, designs, formulas, ideas, programs, software models, algorithms, developments, experimental works, protocols, methods, knowledge, know-how, skill, experience, data and results (including, but not limited to pharmacological, toxicological and non-clinical and clinical data and results), compilations of data, other works of analytical and quality control data, results, descriptions, compositions of matter, regulatory materials and strategies related to or covering a Compound or a Licensed Product which as of the Effective Date (i) is controlled by or hereafter owned or controlled by Licensor or its Affiliates (ii) is not generally known, (iii) is not covered by any Licensor Patent and (iv) is necessary for the research, Development, manufacture, use, sale, distribution, importation, exportation or Commercialization of the Licensed Products in the Territory.

(23) "**Licensor Patents**" means all patents and patent applications (whether provisional or non-provisional), including continuations, continuations-in-part, divisions, renewals, counterparts, reissues, reexaminations and extension of any of the foregoing, that (i) as of the Effective Date and during the Term are owned or Controlled by Licensor or its Affiliates and (ii) claim, cover, or would be practiced by, the research, Development, manufacture, use, sale, distribution, importation, exportation or Commercialization of the Licensed Product.

(24) "**Licensor Technology**" means the Licensor Patents and the Licensor Know-How.

(25) "**Milestone Payment**" has the meaning ascribed to it in Section 6.4.

(26) "**NDA**" means a new drug application and all amendments and supplements thereto filed with regulatory authorities, including all documents, data and other information concerning pharmaceutical products which are necessary for gaining the Regulatory Approval to Commercialize such pharmaceutical product within the Territory.

(27) "**Net Sales**" means gross amounts invoiced by the Licensee to a Third Party, in accordance with generally accepted accounting principles in the Territory, for sales of the Licensed Product, less the following, to the extent included in such gross invoiced sales or otherwise directly paid or incurred by Licensee, sublicensee(s) or such Third Party: [***] The Net Sales shall not include any transfer between Licensee and its sub-licensee(s) for resale.

(28) "**Product Milestone Event**" has the meaning ascribed to it in Section 6.2.

(29) "**Regulatory Approval**" means the issuance or granting of all approvals necessary to Commercialize the Licensed Product in the Territory.

(30) "**Regulatory Authority**" means a regulatory authority or governmental entity having responsibility, jurisdiction, and authority to approve Commercializing of pharmaceutical products within the Territory.

(31) "**Royalty**" has the meaning ascribed to it in Section 7.1.

(32) "**Term**" has the meaning ascribed to it in Section 15.1.

(33) "**Territory**" means Japan.

(34) "**Third Party**" means an entity other than Licensor, Licensee or the Affiliates of Licensor or Licensee.

(35) "**Third Party Compensation**" has the meaning ascribed to it in Section 11.4.

(36) "**Trademark**" means a trademark used solely for the Licensed Product within the Territory as selected in accordance with provisions in Article 10 whether registered or not.

(37) "**Valid Licensed Patents**" means issued patents within the Licensed Patent(s), with respect to the Territory, that: (a) have not been revoked, declared unenforceable or unpatentable, or held invalid by a court or other government agency of competent jurisdiction that is unappealable or unappealed within the time allowed for the appeal; (b) have not been admitted to be rendered invalid or unenforceable through reissue, disclaimer, or otherwise; and (c) have not been finally cancelled, withdrawn, abandoned or rejected by any governmental agency of competent jurisdiction.

Article 2 License Grant

2.1 Licensor hereby grants to Licensee an exclusive royalty-bearing, non-transferable license in the Territory under the Licensed Patents and the Licensor Know-How to Develop, research, use, obtain and maintain the Regulatory Approval for, and to Commercialize the Licensed Product.

2.2 Subject to the prior written consent of the Licensor, which consent shall not be unreasonably withheld, Licensee shall have the right to grant sublicenses under the license granted pursuant to Section 2.1 above in order to Develop and Commercialize the Licensed Product. Licensee shall remain responsible for any and all sub-licensee(s)' actions as if such actions had been made by Licensee.

Article 3 Development

3.1 Licensor shall disclose the Licensor Know-How to Licensee, solely as reasonably necessary and sufficient to Develop, obtain and maintain the Regulatory Approval for, and Commercialize the Licensed Product. Such disclosure of the Licensor Know-How will be made promptly after the execution of this Agreement, and from time to time thereafter as Licensor acquires or generates additional Licensor Know-How. It is agreed that without any required authorization, waiver of authorization, or exemption under applicable privacy laws, no patient-specific information will be included in the Licensor Know-How. It is further agreed that if Licensor discloses Licensee any patient-specific information hereunder, Licensee shall only use or permit use of same for the purposes under which Licensor received such information and for no other purpose without express patient authorization.

3.2 Licensee shall make and shall cause its sub-licensee(s) to make Commercially Reasonable Efforts to carry out the Development of the Licensed Product necessary to obtain the Regulatory Approval at its own expense and risk except as otherwise provided in this Agreement. Licensor shall make reasonable efforts to support the Development and cooperate with Licensee to obtain the Regulatory Approval.

3.3 Licensee shall provide a reasonable development plan and timelines for the Development, which shall include [***] (the "**Development Plan**") of the Licensed Product(s) necessary for obtaining the Regulatory Approval in the Territory. The Development Plan shall be an integral part of this Agreement as Exhibit B hereto. In case Licensee intends to modify the Development Plan substantially, Licensee shall notify Licensor of such intention as soon as possible, and both Parties shall discuss in good faith the modification of the Development Plan in the JSC (defined below).

3.4 Licensor shall, at Licensee's reasonable request, cooperate with and provide all reasonable assistance to Licensee's Development of the Licensed Products in accordance with the Development Plan, including but without limiting the foregoing:

(a) Licensor shall provide Licensee with all reasonable assistance in obtaining Regulatory Approval for the Licensed Products, including providing necessary documents or supporting data and materials required by Regulatory Authority to obtain Regulatory Approval by Licensee; and/or

(b) Licensor shall keep Licensee reasonably informed in a timely manner of the status of the development activities of Licensor, its Affiliates and its licensees relating to the Compound or any Licensed Product outside the Territory including the safety and efficacy results generated from such activities.

3.5 Licensee will provide a copy or summary of material communication to and from the Regulatory Authority in the Territory either in English or Japanese. Licensee will use Commercially Reasonable Efforts to provide Licensor the important points of such communication in English and Licensor will take care of the translation in case of Japanese. Licensor may give comments on any communication from Licensee to the Regulatory Authority in the Territory, and Licensee shall accept any of the comments which are reasonably acceptable.

3.6 In accordance with, and as more specifically detailed the Development Plan, Licensor shall supply Licensee the Compound and/or Licensed Product required and sufficient for Licensee in timely manner to conduct Development free of charge together with written analytic data to verify such Compound and/or Licensed Product. Licensee shall use the Compound and Licensed Product provided exclusively by Licensor under this Article for Development purpose only.

3.7 Licensor shall bear fifty percent (50%) of the Development costs spent by Licensee limited to Naxitamab and [***] in the clinical trial required for the Development as described in the Developed Plan attached hereto as Exhibit B. For avoidance of doubt, the Development costs under this section include (a) fees for consultations with the Regulatory Authority related to the Development, (b) Regulatory Approval application fee, (c) cost of concomitant drugs used in combination with the Licensed Product in the clinical trial required for the Development, (d) costs for any data and information acquired in the Development used for the approval of the concomitant drug for the use in combination with Licensed Product, Licensee will provide Licensor the information on the budgets for and costs actually incurred in Development by Licensee.

Article 4 Collaboration

4.1 Within [***] days after the Effective Date, the Parties shall establish a cross-functional, joint steering committee (the "Joint Steering Committee" or the "**JSC**"), to serve as a forum for information exchange, discussion and decisions with respect to Development relating to the Licensed Products and the Compound in the Territory.

4.2 The JSC shall be comprised of [***] named representatives of each Party (or such other number as the Parties may agree in writing), each of whom will be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. The JSC will be led by a chairperson appointed by Licensee; provided that, if such chairperson is not reasonably acceptable to Licensor and Licensor so informs Licensee (not more than once per Calendar Year), Licensee shall appoint a replacement chairperson reasonably acceptable to Licensor. The role of the chairperson shall be to convene and preside at the meeting of the JSC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JSC representatives. The JSC may change its size from time to time by mutual consent of the Parties. Each Party may replace one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change. Each Party's representatives on the JSC, and any replacement for any such representative, shall be bound by the obligations of confidentiality set forth in Article 14.

4.3 The JSC shall, consistent with the terms and conditions set forth in this Agreement:

(a) coordinate the Parties' Development and Regulatory Approval activities under this Agreement;

(b) discuss the overall strategy for the Development and Regulatory Approval throughout the Territory;

(c) facilitate communications and discussion between the Parties with respect to the Development;

(d) discuss and approve any substantial amendments or revisions to the Development Plan;

(e) keep track of the implementation of the Development Plan and review and serve as an information-sharing forum for Development, including discussion of the results of the activities being carried out thereunder;

(f) define and coordinate regulatory strategy for the Licensed Product;

(g) resolve disputed matters that may arise in relation to the Development; and

(h) perform any and all tasks and responsibilities that are expressly attributed to the JSC under this Agreement or that are otherwise agreed by the Parties in writing.

4.4 The JSC shall meet, until the Regulatory Approval is obtained or the Development is discontinued by any reason, [***] or more or less often as otherwise agreed by the Parties, by videoconference, teleconference, or in person as agreed by the Parties. The chairperson of the JSC shall be responsible for calling meetings on reasonable prior notice. Prior to any meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting. The JSC shall agree on the minutes of each meeting as promptly as practicable, but in any event within [***] Business Days, following such meeting.

4.5 As appropriate (subject to the discretion of the chairperson of the JSC, with approval not to be unreasonably withheld, conditioned or delayed), and *provided* that a prior written notice (preferably two (2) or more Business Days before the meeting) has been given to the other Party, other employees of the Parties may attend JSC meetings as observers.

4.6 Each Party may also call for special meetings of the JSC with reasonable prior written notice to the other Party to resolve particular matters requested by such Party.

4.7 If the JSC is unable to reach a consensus regarding any technical discussion pertaining to Development matters or regulatory affairs, final decision shall be made by Licensee.

4.8 Each Party shall be responsible for all of its own expenses incurred in connection with participating in all meetings.

Article 5 Approvals

5.1 After the completion of the Development activities necessary to file an NDA for the Licensed Product, Licensee shall use Commercially Reasonable Efforts to file and/or shall cause its sub-licensee(s) file the NDA of such Licensed Product without undue delay and Licensee shall make and/or shall cause its sub-licensee(s) to make its sincere endeavors to obtain the Regulatory Approval in the Territory.

5.2 Licensee hereby grants to Licensor the right to use, cross-reference, file or incorporate by reference any relevant regulatory filings pertaining to the Licensed Products submitted by or on behalf of Licensee in the Territory. Licensor and permitted sublicensees may use such rights of reference solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and Commercializing Licensed Products outside the Territory and in interactions with any Regulatory Authority in connection with Development, manufacturing or Commercialization outside the Territory, subject in each case to Licensor's obligation to provide written notice to Licensee reasonably in advance of any submissions made in connection with such right of reference or such interactions or other communications, in each case in order for Licensee to consult with Licensor and to propose including, adopting or incorporating any reasonable recommendations or instructions in connection with the rights granted under this Section 5.2.

5.3 Prior to Licensee's and/or its sub-licensee(s)' filings of such NDA, Licensee shall give Licensor an advance notice of such filings. Licensee shall furnish Licensor with a copy of the filing documents submitted by Licensee and/or its sub-licensee(s) to the Regulatory Authority for such NDA.

5.4 If any question or comment is raised by the Regulatory Authority to Licensee and/or its sub-licensee(s) in regard to the NDA, Licensee shall give and/or shall cause its sub-licensee(s) to give appropriate answer to the Regulatory Authority in response to such questions or comments. Licensee will provide a copy or summary of material communications regarding such questions or comments either in English or Japanese as soon as practically possible. Licensor may give comments on those communications and Licensee shall accept any of the comments which are reasonably acceptable. Licensor will help Licensee at Licensee's request respond to said questions or comments as Licensor is reasonably able to do so.

5.5 Licensee shall hold and control all Regulatory Approval and applications, amendments or supplements underlying any such Regulatory Approval for the benefit of the Licensor.

5.6 After obtaining Regulatory Approval for the Licensed Product, Licensee will aim to achieve an NHI drug price of [***] yen per treatment course per patient (base on a USD/Yen exchange rate of 1:138) or [***] USD, while the number of vials to be used in a treatment course will depend on the judgment of the Regulatory Authority in the Territory. Licensee shall make a strategic plan for the NHI drug price negotiations with the Regulatory Authority to achieve no less than the aforementioned targeted NHI drug price or over and Licensor shall provide reasonable assistance to such effort by Licensee. In cases of inquiries from Regulatory Authority regarding the COGs of the Licensed Product, Licensor, in its commercially reasonable discretion, shall have the ability, but not the obligation,, directly or indirectly through Licensee, to provide reasonable answers to such inquiries.

Article 6 Initial Payment and Milestone Payments

6.1 Subject to the terms and conditions of this Agreement, Licensee shall pay Licensor the non-refundable, one-time initial payment of two million US dollars (USD 2,000,000) to Licensor within [***] days of the Effective Date.

6.2 Subject to the terms and conditions of this Agreement, promptly following the first occurrence of each of the events set forth below (each, a "**Product Milestone Event**"), whether such Product Milestone Event is achieved by Licensee or its sub-licensee(s), Licensee shall notify Licensor of the occurrence of such Product Milestone Event.:

Product Milestone Events

(1) [***]

(2) [***]

(3) [***]

(4) [***]

6.3 Subject to the terms and conditions of this Agreement, within thirty (30) days from the end of the Calendar Quarter in which any commercial milestone event set forth below (each, a "**Commercial Milestone Event**") is achieved, whether by Licensee or its sub-licensee(s), Licensee shall notify Licensor of the occurrence of such Commercial Milestone Event:

Commercial Milestone Events

(1)	Exceeding Cumulative Total Net Sales of USD [***]:	USD [***]
(2)	Exceeding Cumulative Total Net Sales of USD [***]:	USD [***]
(3)	Exceeding Cumulative Total Net Sales of USD [***]:	USD [***]
(4)	Exceeding Cumulative Total Net Sales of USD [***]:	USD [***]
(5)	Exceeding Cumulative Total Net Sales of USD [***]:	USD [***]

6.4 Licensee shall pay to Licensor the milestone payment set forth in Section 6.2 corresponding to such Product Milestone Event within [***] days after an occurrence of such Product Milestone Event; and the milestone payment set forth in Section 6.3 corresponding to such Commercial Milestone Event by the end of the second month after the end of the Calendar Quarter with the occurrence of such Commercial Milestone Event (each, a "**Milestone Payment**").

Article 7 Royalty Payments

7.1 In addition to the foregoing payments, during the Term of this Agreement, Licensee shall pay to Licensor a quarterly royalty ("**Royalty**") equal to [***] percent ([***]%) of the Net Sales in a certain Calendar Year.

7.2 With respect to any Calendar Year, [***] for Licensed Product held by Licensee [***] previously paid by Licensee when the [***] (determined on [***] basis as defined by US GAAP) [***] imposed by the Ministry of Health, Labor and Welfare. The [***] will be used to [***].

7.3 Notwithstanding the foregoing, after the last Valid Licensed Patents, are expired, and then only if generic/biosimilar products are launched which capture [***] percent ([***]%) of the market for the Licensed Product, the Royalty shall be [***] percent ([***]%) of the Net Sales commencing with the next month. Notwithstanding the foregoing, the Parties will discuss Royalty rate adjustments in case the NHI drug price is not achieved as aimed under Section 5.6.

7.4 Within [***] Business Days from the end of each Calendar Quarter, Licensee shall deliver to Licensor a written report showing its computation of the Royalty during such Calendar Quarter including any inventory of Licensed Product subject to the credit memo under Section 7.2 above, if any. Such report shall state the gross sales of the Licensed Product(s), the amount deducted and the Net Sales for the relevant Calendar Quarter.

7.5 Licensor shall issue and send Licensee an invoice for the Royalty for each of the Calendar Quarter after receiving the report under Section 7.4. Licensee shall pay such Royalty within [***] days of the invoice date, payable in US Dollars.

7.6 Licensee shall keep and cause its sub-licensee(s) to keep complete, true and accurate books and records with respect to the Net Sales, the Royalty payable by Licensee to Licensor under Article 7 and the calculation thereof in sufficient detail to enable the determination of such Royalty.

7.7 Licensor shall have the right during the Term of this Agreement and for a period of [***] thereafter, to have an independent certified public accounting firm, either mutually acceptable to Licensee and Licensor or nominated by Licensor among the large international accounting firms examine the relevant books and records of the accounts of Licensee, and/or its sub-licensee(s) to determine whether the Royalty has been accurately reported by Licensee for the preceding three (3) years period. Such examination shall not take place more often than one (1) time during each Calendar Year. All expenses for such examination shall be borne by Licensor; provided, however, that Licensee shall reimburse Licensor for all of such expenses if an underpayment of more than [***] percent ([***]%) is discovered in Licensee's reports of the Royalty for the audit period. Licensor shall cause its accounting firm to retain all financial information subject to review under this paragraph in strict confidence, and Licensee shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Licensee regarding such financial information. The accounting firm shall disclose to Licensor only whether the Royalty reports are correct or not and the amount of any discrepancy, if any. Licensor shall treat all such financial information as Licensee's Confidential Information.

Article 8 Payments

8.1 All payments due to Licensor hereunder shall be remitted by wire transfer to the following bank account of Licensor:

Bank Name:	[***]
Bank Address:	[***]
Bank SWIFT CODE:	[***]
Banking Routing Number:	[***]
Account Number:	[***]
Account Name:	[***]

When conversion of payments from any foreign currency to US dollars is required, such conversion shall be at an exchange rate equal to the telegraphic transfer middle rate published [***]

8.2 In the event of any withholding taxes being levied on payments under Articles 6 and 7 due to Licensor under any applicable Laws or treaties, such taxes shall be withheld by Licensee from the said payment. Licensee shall pay such taxes on behalf of Licensor to the appropriate tax authorities and promptly furnish Licensor with official certificate of payment of such taxes to permit Licensor to claim a tax credit therefor. If Licensor is entitled under any applicable tax treaty to reduction or exemption of applicable withholding tax and intends to benefit from such reduction or exemption under treaty, Licensor shall submit the required forms and documentation to the appropriate tax authorities through Licensee before the payments are made. Licensor shall provide any such required forms and documentation to Licensee at least fifteen (15) Business Days prior to the time that the payments are due.

8.3 In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at a rate per annum that is [***] percentage points ([***]%) above the U.S. Prime Rate of interest as reported by Bloomberg on the date such payment is due; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate.

Article 9 Forecast, Delivery and Orders Forecast

9.1 Subject to the terms and conditions of this Agreement, for the purpose of Commercialization of the Licensed Product in the Territory, Licensor shall be the exclusive supplier to Licensee of the Licensed Products in unlabeled vials and shall supply the Licensed Products sufficient for Commercialization in timely manner to Licensee on [***]. To avoidance of doubt, Licensee has the right to furnish final package of Licensed Product for the Commercialization in the Territory.

9.2 In consideration for the supply of the Licensed Product in Section 9.1 above, Licensee shall pay to Licensor a price ("Supply Price") equal to the cost of goods sold ("**COGS**") plus [***]% per vial, where COGS means the actual manufacturing and packaging costs as calculated under US GAAP.

9.3 Licensee shall have the right during the Term of this Agreement and for a period of [***] thereafter, to have an independent certified public accounting firm, either mutually acceptable to Licensor and Licensee or nominated by Licensee among the large international accounting firms examine the relevant books and records of the accounts of Licensor to determine whether the COGs have been accurately calculated and reflected by Licensor to the Supply Price.

9.4 In case of the marked increase in COGS (in yen terms) due to economic changes such as currency exchange fluctuation and/or rising raw material costs placing Licensee in an economically and commercially difficult situation to continue the Development, Commercialization and other activities under this Agreement, the Parties will discuss in good faith to review and amend the provisions of this Agreement.

9.5 Licensor and Licensee shall conclude a supply and quality agreement based on mutual agreement that defines detailed terms and conditions regarding supply and quality of the Licensed Products respectively.

Article 10 Trademark

10.1 The Trademark to be used by Licensee on the Licensed Product(s) shall be selected by Licensee and shall be owned by Licensee. Licensee shall be responsible for the registration and maintenance of such selected Trademark at its expense and risk.

10.2 Notwithstanding the foregoing, if Licensee desires to use any trademark owned by Licensor by itself or through its sub-licensee(s) in connection with the Commercialization of the Licensed Product(s) in the Territory, Licensor, after reviewing and approving Licensee's written proposal for the use of the trademark, may in its sole discretion, grant Licensee a limited, royalty-free license to use such trademark in connection with the Commercialization of the Licensed Product. Licensee shall have right to use such Licensor's trademark without any additional payment other than Milestone Payments and Royalty defined in Articles 6 and 7. Licensee will indemnify and hold harmless Licensor for any commercial liabilities growing out of such use.

Article 11 Infringement

11.1 Whenever either Party becomes aware of any possible infringement of the Licensed Patents by a Third Party, such Party shall promptly notify the other Party of any such infringement and shall provide the other Party with any available evidence of such infringement.

11.2 Licensor shall bring any action including lawsuit for infringement of the Licensed Patents. Any infringement action brought by Licensor shall be solely at Licensor's expense, and Licensee or its sub-licensee(s) shall provide reasonable assistance at Licensor's expense in the prosecution of such action. Licensor shall not prosecute or settle such action in any manner that affects Licensee's rights in the Licensed Patents without the prior written consent of Licensee. In the event that monetary damages are awarded or obtained by Licensor whether by judgment, award, decree, settlement or otherwise, as a result of any infringement action brought by Licensor, the money actually received shall be divided appropriately between Licensor and Licensee with reference to the relative monetary injury suffered by the Party by reason of the infringement, after first deducting the expenses incurred by Licensor in filing, prosecuting, and maintaining such action.

11.3 In the event a Third Party commences or threatens to commence any action including lawsuit against Licensee, alleging infringement of such Third Party's intellectual property rights by Licensee's or its sub-licensee(s)' conducts or behavior of Development, Commercialization or use of the Licensed Product, Licensee shall give prompt notice ("**Infringement Notice**") thereof to Licensor. Licensee shall have the right, but not the obligation, to control the defense and settlement of any such action. If Licensee fails to exercise such right within [***] days from the Infringement Notice, Licensor shall have the right, but not the obligation, to control the defense and settlement of any such action solely on its own behalf. Either Party shall not have the right to settle any such action in any manner that could have any adverse effect on the other Party without the prior written consent of such other Party.

11.4 Licensee shall be entitled to deduct from any amounts payable to Licensor under this Agreement (a) any amounts required to be paid to a Third Party by Licensee or its sub-licensee(s) pursuant to 11.3 in order to satisfy an award of damages or comply with a settlement agreement arising out of any claims that Development, Commercialization, or use of the Licensed Products by Licensee or its sub-licensee(s) independently of any Licensee Intellectual Property infringes any intellectual property rights of such Third Party and (b) any costs and expenses (including without limitation reasonable attorney's fees) incurred in connection with defending and/or settling any such claims and/or any invalidity, infringement or other actions associated with (a). Further, if the Parties agree that Licensee or its sub-licensee(s) is required to obtain a license from any Third Party in order to exercise its rights hereunder to Develop, Commercialize or use any Licensed Product, and is required to pay to such Third Party a royalty, milestone payments or other fees in consideration for the grant or maintenance of such license ("**Third Party Compensation**") it shall seek to enter such an agreement. Prior to finalizing such agreement, Licensee shall give Licensor an opportunity to review and approve any proposal. Licensor will not unreasonably withhold its approval. If any such agreement is approved by Licensor, the Licensee shall be entitled to deduct an amount equal to [***] percent ([***]%) of such Third Party Compensation paid by or on behalf of Licensee to such Third Party during a Calendar Quarter, from the amounts of Licensee's Milestone Payment or Royalty otherwise due to Licensor in accordance with Article 6 and Article 7 in a next Calendar Quarter. For clarity, Licensee may carry over and apply any amount of aforementioned reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter, to any subsequent Calendar Quarter(s) in which Royalty or Milestone Payment are due.

Article 12 Adverse Event

12.1 Subject to the restrictions of any applicable Laws, each Party shall disclose to the other Party all reports and information received or obtained from any sources whether inside or outside the Territory with respect to any adverse events of the Compound and/or a product containing the Compound.

12.2 Licensee shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Licensed Products in the Territory.

12.3 In addition to the obligations set forth in Section 12.1 above, Licensee shall conduct relevant post marketing surveillance activities to comply with the regulations in the Territory at its sole expense and responsibility.

12.4 Detailed terms and conditions regarding the exchange of drug safety information of Licensed Products shall be concluded separately in Pharmacovigilance Agreement between both Parties.

Article 13 Intellectual Property and Intellectual Property Prosecution

13.1 Except as expressly provided herein, Licensor shall solely and exclusively own and hereby reserves all rights, title, and interest in and to any Licensor Technology and all data, inventions, discoveries and improvements including, but not limited to, formulation method, preparation method, administration method and clinical application relating to the Compound and/or the Licensed Product, whether patentable or not, developed by Licensor, its Affiliates, or in conjunction with Licensee or on behalf of Licensee upon receiving Licensee's written consent hereto, and no rights, title or interest in and to the Licensor Technology or any other intellectual property right is granted or otherwise conveyed by Licensor to Licensee, whether by implication, estoppel, or otherwise.

13.2 Licensee shall own and reserve all rights to any data, inventions, discoveries and improvements including, but not limited to, formulation method, preparation method, administration method and clinical application relating to the Compound and/or the Licensed Product, whether patentable or not, developed hereunder only by Licensee or on behalf of only Licensee without using Licensor Know-How (collectively, "**Licensee's Intellectual Property**").

13.3 Licensor shall have an exclusive royalty-free license to use the Licensee's Intellectual Property outside the Territory. Licensee shall provide Licensor with the appropriate documentation as may be needed to evidence such license.

13.4 Licensor shall have responsibility for the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of the Licensed Patents reasonably needed to grant license stipulated in Section 2.1. In case of any patent application within the Licensed Patents is filed by Licensor in the Territory, Licensor shall give Licensee an advance notice of its filing date and serial number with a copy of such patent application to be filed.

13.5 If Licensor, in its sole discretion, decides to abandon the preparation, filing, prosecution or maintenance of any patent or patent application in the Licensed Patents, then Licensor shall notify Licensee in writing thereof, and following the date of such notice, Licensee shall have the right to assume control, at its sole cost, for the preparation, filing, prosecution and maintenance of such patents and patent applications, and shall have the right to offset the cost thereof against amounts owing to Licensor hereunder. If Licensee fails to make such an election, Licensor shall retain the right in its sole discretion to continue prosecution and maintenance of such Licensed Patent or discontinue such work.

13.6 Licensee shall have the sole right but not the obligation at its own expense to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of the Licensee's Intellectual Property worldwide. Licensee shall keep Licensor informed of progress with regard to the prosecution and maintenance of Licensee's Intellectual Property in the Territory, Licensee will consult with, and consider in good faith the results and suggestions of, Licensor with respect to strategies for the filing and prosecuting Licensee's Intellectual Property in the Territory.

13.7 If Licensee, in its sole discretion, decides to abandon the preparation, filing, prosecution or maintenance of any patent or patent application in the Licensee's Intellectual Property, then Licensee shall notify Licensor in writing thereof, and following the date of such notice, Licensor shall have the right to assume control, at its sole cost, for the preparation, filing, prosecution and maintenance of such patents and patent applications, and shall have the right to offset the cost thereof against amounts owing to Licensee hereunder. If Licensor fails to make such an election, Licensee shall retain the right in its sole discretion to continue prosecution and maintenance of such Licensee's Intellectual Property or discontinue such work.

13.8 It is hereby acknowledged by the Parties that Licensor [***]. The Licensee shall make Commercially Reasonable Efforts to timely provide any requested information and documentation [***].

Article 14 Confidential Information

14.1 Either Party shall treat all information (whether technical or non-technical) obtained from the other Party ("**Confidential Information**") as secret and confidential if designated as such, and shall not supply or disclose to any Third Party any Confidential Information during the Term of this Agreement and for a period of [***] years thereafter. The foregoing obligations of confidentiality and non-use shall not apply to:

(a) information which at the time of disclosure is publicly known;

(b) information which thereafter lawfully becomes publicly known other than through disclosure by the receiving Party;

(c) information which, as evidenced in the receiving Party's written records, was known by it prior to the disclosure thereof by the disclosing Party;

(d) information which is disclosed to the receiving Party by a Third Party not under obligation of confidentiality to the disclosing Party with respect to said disclosure; or

(e) information which, as evidenced in the receiving Party's written records, the receiving Party establishes or is subsequently developed by an employee of the receiving Party without actual knowledge of the Confidential Information.

For the avoidance of doubt, the Confidential Information includes the 'Information' as defined in and disclosed to the other Party under the CONFIDENTIALITY AGREEMENT dated September 22, 2022 between the Parties.

14.2 Notwithstanding the foregoing, both Parties shall be entitled to use, supply or disclose the Confidential Information for the purpose of implementing this Agreement to any of the following:

(a) either Party's Affiliates, directors, officers, employees and representatives who have a need to know, provided that the recipients have been informed of this Agreement and such Party shall be responsible for such recipients' use, supply or disclosure of the Confidential Information as if such use, supply or disclosure had been made by such Party;

(b) either Party's contract manufacturers, contract research organizations, professional service providers, distributors, sub-licensees, attorneys, accountants, tax advisors, or other professional advisors or consultants who have a need to know, provided that the recipients have been informed of and are bound to secrecy obligations substantially similar to those in this Agreement;

(c) Licensee's shareholders;

(d) investors and financial institutions to whom either party is necessary to provide Confidential Information for the purpose of its financing, provided that the recipients have been informed of and are bound to secrecy obligations substantially similar to those in this Agreement; or

(e) the Regulatory Authorities which have been advised of the confidential status of the Confidential Information.

14.3 In the event the receiving Party is required by a valid legal order of any governmental, regulatory, or supervisory authority to disclose any Confidential Information received under this Agreement, the receiving Party may disclose such Confidential Information to the extent necessary to comply with such requirement; provided that receiving Party gives the disclosing Party reasonable notice of its intent to disclose such information.

Article 15 Duration and Termination

15.1 This Agreement shall become effective on the Effective Date and shall, unless otherwise terminated sooner as provided hereunder, remain in effect until the later of (i) the date of the Licensed Patents expiration including any granted PTE, (ii) the date after which biosimilar market entry have garnered more than [***]% of the Product market, or (iii) ten (10) years from the first Launch ("**Term**").

15.2 In the event of any material breach of this Agreement by either Party, the Party not in breach shall have the option to terminate this Agreement if such breach is not cured by the other Party within the period stipulated for such cure (not to be less than [***] days) in the written notice sent by the non-breaching Party relating to the material breach.

15.3 Licensee shall have the right and option to terminate this Agreement immediately at any time in case any safety issues arise with Compound or any product using Compound, and/or it is not economically or commercially reasonable to Develop or Commercialize Licensed Product in the Territory, by [***] days prior written notice to Licensor without any liability. Neither Party shall disclaim any rights or make any claims to the other Party except for those legally required for terminating this Agreement and for those duly obtained under this Agreement prior to the effective date of termination.

15.4 Either Party shall have the right and option to terminate this Agreement immediately at any time, by notice in writing to the other Party, in the event that such other Party:

(a) is unable to pay, or admits its general inability to pay to any creditor, or takes any step inconsistent with an ability to pay its debts as they fall due and payable;

(b) files for voluntary, or any Third Party files against such other Party, a petition of liquidation, bankruptcy, reorganization, compulsory composition, dissolution or similar proceedings;

(c) passes any resolution for or permits any proceedings for its dissolution; or

(d) abolishes its business.

Article 16 Effect of Expiration or Termination

16.1 Upon the expiration of this Agreement in the Territory, Licensee shall thereafter have an irrevocable, fully paid-up, non-exclusive license under the Licensed Patents and Licensor Know-How to Develop and Commercialize the Licensed Product in the Territory and, in order thereto, to use and exploit the Licensed Patents and Licensor Know-How.

16.2 The License and Licensor's Trademark (if used under Section 10.2) granted under this Agreement shall become irrevocable, fully paid-up, non-exclusive license and Licensee may continue to Commercialize the Licensed Product under the Regulatory Approval, if:

(a) this Agreement expires pursuant to Section 15.1;

(b) this Agreement is terminated by Licensee due to material breach of Licensor pursuant to Section 15.2; or

(c) this Agreement is terminated by Licensee pursuant to Section 15.4.

16.3 The Regulatory Approval of Licensed Product shall be transferred to Licensor at no cost to Licensor, if:

(a) this Agreement is terminated by Licensor due to material breach of Licensee pursuant to Section 15.2; or

(b) this Agreement is terminated by Licensor pursuant to Section 15.4.

16.4 Upon the expiration or termination of this Agreement in its entirety, except in the case of Sections 16.1 and 16.2, each Party shall without undue delay return to the other Party, delete or destroy all Confidential Information including all copies thereof, except that each Party (a) may retain one complete copy of the same for the purpose of determining its obligations hereunder and (b) shall not be required to erase electronic files created in the ordinary course of business during automatic system back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

16.5 Any expiration or termination of this Agreement shall not relieve either Party's obligations set forth in Sections 13.2, 21.7 and 21.8, and Articles 12, 16, and 18 hereof, and the confidential obligations in Article 14 shall survive for the period ascribed therein.

Article 17 Warranty

17.1 Each Party hereby represents, warrants and covenants that, as of the Effective Date, such Party is duly organized, validly existing under the Laws of its state or country of incorporation and has full corporate power and authority to enter into this Agreement and carry out the provisions hereof.

17.2 Each Party hereby represents and warrants that, as of the Effective Date, such Party is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder.

17.3 Each Party hereby represents, warrants and covenants that, as of the Effective Date: (a) this Agreement is legally valid and enforceable in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar Laws, from time to time in effect, affecting creditors' rights generally; and (b) the execution, delivery and performance of this Agreement by such Party does not, and will not during the Term of this Agreement, conflict with any agreement, instrument or understanding to which it is a party or by which it is bound, nor to the best knowledge of each Party as of the Effective Date will such execution, delivery and performance violate any applicable Laws.

17.4 Licensor represents and warrants that, as of the Effective Date:

(a) it has sufficient legal and/or beneficial title to the Licensed Patents and the Know-How, with the right to grant (sub)licenses, necessary to grant to Licensee the rights it purports to grant to Licensee as provided under this Agreement;

(b) to the best of Licensor's knowledge, there are no claims or demands of any person, firm, or corporation pertaining to the Licensed Patents and to the best of its knowledge, no proceedings have been instituted or are pending or threatened, which challenge the rights of Licensor under the Licensed Patents;

(c) to the best of its knowledge, there are no matters which would be reasonably expected to affect the validity of the Licensed Patents;

(d) to the best of its knowledge, there are no patents owned by Third Party, or other proprietary rights of Third Party, that would be infringed or misappropriated by Developing or Commercializing the Licensed Product in the Territory;

(e) it has received no notice from any Third Party that Developing, manufacturing or Commercializing the Licensed Product infringe the proprietary rights of such Third Party;

(f) Exhibit A is a true, complete and current listing of the patents owned or controlled by Licensor that relate to the Compound and the Licensed Product;

(g) there is no pending or, to the best of its knowledge, overtly threatened action by relevant Regulatory Authorities that will have a material adverse effect on Licensee's ability to conduct the Development of the Compound and Licensed Product in the Territory;

(h) Licensor has disclosed or made available to Licensee for review all Licensor development data, Regulatory materials, and other material information relating to the safety and efficacy of the Compound and the Licensed Product, and all such information is complete and accurate in all material respects;

(i) it has not engaged in any conduct or activity which could lead to any debarment action, and, to the best of its knowledge, none of the entities, laboratories or clinical sites, or their employees, representatives or agents participating in any pre-clinical or clinical studies prior to the Effective Date has been debarred;

(j) Licensor and its officers, directors, employees, and Affiliates shall perform all obligations under this Agreement in compliance with applicable Laws;

(k) Licensor will not engage in deceptive, misleading, illegal or unethical practices, representations, statements or conduct that are or might be detrimental to Licensee, the Licensed products, patients or the public;

(l) to the best of its knowledge, Licensor has no actual or perceived conflict of interest which would adversely affect the performance of its obligations under this Agreement;

(m) Licensor will comply with all applicable national and international anticorruption laws (including the US FCPA which prohibit bribery, offering, promising or giving any financial or other advantage and the payment of money or anything of value to government officials, political parties, candidates and any other person for the purpose of corruptly obtaining or retaining business; and

(n) Licensor is not aware of any fact, act or omission that would constitute an inappropriate inducement under applicable anti-bribery or anti-corruption laws.

17.5 Licensee represents and warrants that, as of the Effective Date:

(a) it has not engaged in any conduct or activity which could lead to any debarment action, and, to the best of its knowledge, neither any of its officers nor directors, employees, Affiliates, and sub-licensees are debarred or disqualified by any Regulatory Authority in the Territory in connection with any of their activities relating to the Compound or Licensed Products;

(b) Licensee and its officers, directors, employees, and Affiliates shall perform all obligations under this Agreement in compliance with applicable Laws;

(c) Licensee will not engage in deceptive, misleading, illegal or unethical practices, representations, statements or conduct that are or might be detrimental to Licensor, the Licensed Products, patients or the public;

(d) to the best of its knowledge, Licensee has no actual or perceived conflict of interest which would adversely affect the performance of its obligations under this Agreement;

(e) Licensee has and will maintain the necessary expertise to perform its obligations under this Agreement;

(f) Licensee will promote the Licensed Products in accordance with all applicable laws, regulations, this Agreement and its self-regulatory codes; and

(g) Licensee will comply with all applicable national and international anticorruption laws (including the US FCPA which prohibit bribery, offering, promising or giving any financial or other advantage and the payment of money or anything of value to government officials, political parties, candidates and any other person for the purpose of corruptly obtaining or retaining business.

17.6 During the Term of this Agreement, neither Party shall knowingly use any employee, representative, agent, assistant or associate who has been debarred by any regulatory authority in connection with any of the activities to be carried out under this Agreement.

Article 18 Indemnifications; Hold Harmless

18.1 Licensee shall indemnify, defend and hold Licensor and Licensor's Affiliates and their respective officers, directors, employees, partners and agents ("**Licensor Indemnitees**") harmless from and against any and all liability, damages, cost or expenses (including reasonable attorneys' fees and disbursements) incurred as a result of any claim made or suit brought by a Third Party against Licensor Indemnitees arising out of the Development and Commercialization of the Licensed Product by Licensee or Licensee's breach of any warranties, representations or covenants contemplated in this Agreement, except to the extent that such liability, damages, costs or expenses are caused by the negligence or intentional misconduct or breach of covenant in this Agreement by the Licensor Indemnitees. Upon receipt of any such claim or suit by any of the Licensor Indemnitees, Licensor or such Licensor Indemnitees shall promptly notify Licensee in writing of such claim or suit and shall permit Licensee to defend against and control the defense of such claim or suit, provided that Licensee shall not compromise or settle such claim or suit without the prior written approval of Licensor. Licensor or any Licensor Indemnitees shall have the right to participate in the defense of such claim or suit at its own expense; provided that Licensor or such Licensor Indemnitees shall not compromise or settle such claim or suit without the prior written approval of Licensee.

18.2 Licensor shall indemnify, defend and hold Licensee, Licensee's Affiliates and its sub-licensee(s) and their respective officers, directors, employees, partners and agents ("**Licensee Indemnitees**") harmless from and against any and all liability, damages, costs or expenses (including reasonable attorney's fees and disbursements) incurred as a result of any claim made or suit brought by a Third Party against Licensee Indemnitees arising out of Licensor's manufacture and/or sale of the Compound or Licensed Product supplied to Licensee that does not conform to its specifications or is not made in compliance with GMP or Licensor's breach of any warranties, representations or covenants contemplated in this Agreement, except to the extent that such liability, damages, costs or expenses are caused by the negligence or intentional misconduct or breach of covenant in this Agreement by the Licensee Indemnitees. Upon receipt of any such claim or suit by any of the Licensee Indemnitees, Licensee or such Licensee Indemnitees shall promptly notify Licensor in writing of such claim or suit and shall permit Licensor to defend against and control the defense of such claim or suit, provided that Licensor shall not compromise or settle such claim or suit without the written approval of Licensee. Licensee or any Licensee Indemnitees shall have the right to participate in the defense of such claim or suit at its own expense; provided that Licensee or any Licensee Indemnitee shall not compromise or settle such claim or suit without the prior written approval of Licensor.

Article 19 Remedies

19.1 The Parties acknowledge that any breach of this Agreement may cause irreparable harm to the other Party and agree that Licensor's or Licensee's remedies for any breach by the other Party may include, in addition to damages and other available remedies, injunctive relief against such breach.

19.2 It is expressly understood that, except with regard to each Party's obligation to indemnify the other Party for indemnification liability to a Third Party under Article 18, neither Party will be liable for any special, consequential, indirect, incidental or punitive damages, under any cause of action, whether under any contract, negligence, strict liability or other legal or equitable theory, with respect to any subject matter of this Agreement and whether or not such Party or its agents have been advised of the possibility of such damage. This limitation shall apply notwithstanding any failure of essential purpose of any limited remedy provided herein.

Article 20 Successors and Assigns.

20.1 Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed, except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate); provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any sale of all or substantially all of the assets of the Party that relate to this Agreement to a Third Party, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise (a "Sale Transaction"; such Third Party a "Third Party Acquirer"); provided that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by all obligations of the assigning Party under this Agreement.

Article 21 Miscellaneous

21.1 Disclaimer. Except as otherwise expressly set forth in this Agreement, neither Party makes any representations or extends any warranties of any kind, either express or implied, including, but not limited to, warranties of merchantability, fitness for a particular purpose or non-infringement.

21.2 Force Majeure. Any delay in the performance of any of the duties or obligations of either Party shall not be considered a breach of this Agreement and the time required for performance shall be extended for a period equal to the period of such delay, provided that such delay caused by or is the result of any acts of God, acts of the public enemy, wars, terrorism, insurrections, riots, embargoes, fires, explosions, floods, earthquakes, shortages of energy, breach or failure on the part of any Third Party, or other unforeseeable causes beyond the control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible.

21.3 Severability. In the event that any one or more of the provisions of this Agreement should for any reason be held by a court or other governmental authority of competent jurisdiction to be invalid, illegal or unenforceable, to the extent practicable such provision or provisions shall be reformed or renegotiated to as nearly approximate the original reasonable intent of the Parties as possible and the validity, legality or enforceability of the remaining provisions shall in no way be affected or impaired thereby.

21.4 Non-waiver. A Party's failure to exercise or delay in exercising any right, remedy, power or privilege hereunder shall not operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof, or the exercise of any other right, remedy, power or privilege.

21.5 Accrued obligation. Expiration or termination of this Agreement for any reason shall not release any Party from any liability which at the time of such expiration or termination has already accrued to the other Party or which is attributable to a period prior to such expiration or termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

21.6 Independent contractor. The relationship between Licensor and Licensee is that of independent contractors. Licensor and Licensee are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

21.7 Governing law. This Agreement shall be governed by the laws of England and Wales without regard to principles of conflicts of law thereof.

21.8 Dispute resolution. All disputes arising out of or in connection with this Agreement shall be subject to the exclusive jurisdiction of the courts of England.

21.9 Captions. The captions of paragraphs in this Agreement are for convenience only, and this Agreement shall not be construed or interpreted by reference to such captions.

21.10 Notice. All notices, given by one Party hereto to the other Party hereunder shall be in writing and made by registered or certified air mail, facsimile, express overnight courier or delivered personally to the following addresses of the respective Parties:

If to Licensor: Y-mAbs therapeutics, Inc.
230 Park Avenue, Suite 3350,
New York, NY 10169, USA
Attention: [***]
E-mail: [***]

with a copy to (which will not constitute notice)
Attention: [***]
Email: [***]

If to Licensee: Nobelpharma Co., Ltd.
NMF Kayabacho Building, 1-17-24, Shinkawa,
Chuo-ku, Tokyo 104-0033, Japan
Attention: [***]
Email: [***]
[***]

The notice under the preceding paragraph, unless otherwise provided, shall be deemed to be effective: (a) upon receipt if personally delivered or e-mailed, or upon transmitted by facsimile with evidence of transmission; (b) on the tenth (10^{th}) business day following the date of mailing if sent by registered or certified air mail; or (c) on the third (3^{rd}) business day following the date of transmission if sent by express overnight courier. Either Party may change its address listed above by sending notice to the other Party.

21.11 Publicity. Neither Party shall originate any publicity, news release, publication or public announcement, written or oral, whether to the public press, stockholders or otherwise, concerning this Agreement or the subject matter hereof without the prior written consent of the other Party. The foregoing restriction shall not apply to information which, in the opinion of legal counsel of the Party intending to make disclosure, is legally required to be disclosed by law, regulation or court order, including responding to subpoena or other legal process, or fulfilling the obligations of either Party (or any successor thereto) as a publicly traded corporation under any applicable laws and regulations.

21.12 Execution in counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

21.13 Entire agreement. This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof. This Agreement shall supersede any prior agreement between the Parties hereof. No term or provision of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by a written instrument specifically referring to this Agreement.

[remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed the Agreement as of the date first above written.

On behalf of **Y-mAbs Therapeutics, Inc.** as Licensor:

By: /s/ Mike Rossi
Name: Mike Rossi
Title: CEO

By: /s/ Thomas Gadd
Name: Thomas Gad
Title: Founder, Vice-Chair, CBO

On behalf of **Nobelpharma Co., Ltd.** as Licensee:

By: /s/ Jin Shiomura
Name: Jin Shiomura
Title: Managing Director & CEO

Exhibit 99.1

Y-mAbs and Nobelpharma Announce Exclusive License and Distribution Agreement for DANYELZA® (naxitamab-gqgk) in Japan

New York, NY and Japan, November 4, 2024 – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel radioimmunotherapy and antibody-based therapeutic products for the treatment of cancer, and Nobelpharma Co., Ltd. today announced that they have entered into an exclusive license and distribution agreement for the development and commercialization in Japan of DANYELZA for the treatment of patients with relapsed/refractory high-risk neuroblastoma and, upon agreement by the parties, potentially relapsed osteosarcoma.

Under the terms of the agreement, Nobelpharma will employ its regulatory, marketing, sales and access expertise to carry out development work and to submit DANYELZA for approval by Japanese regulatory authorities, and to market, sell, and distribute DANYELZA in Japan, if approved. Pursuant to the agreement, Y-mAbs will receive an upfront payment of $2.0 million from Nobelpharma in connection with entering into the agreement and is entitled to receive up to $31.0 million in product and commercial milestone payments in addition to royalties in the low double digits on commercial sales on DANYELZA, if successfully approved and commercialized in Japan.

"Our exclusive license and distribution agreement with Nobelpharma in Japan is an important step in our continued global expansion efforts of DANYELZA," said Michael Rossi, President and Chief Executive Officer of Y-mAbs. "If approved in the region, we believe DANYELZA can deliver a meaningful impact to patients in Japan fighting relapsed/refractory high-risk neuroblastoma and improve long-term quality of life for these children."

"We believe that Nobelpharma is the right partner for Y-mAbs in Japan, and we are excited to work with Nobelpharma towards the potential approval and commercial launch of DANYELZA in the region," said Thomas Gad, Founder and Chief Business Officer of Y-mAbs. "DANYELZA, if approved in Japan for relapsed/refractory high-risk neuroblastoma, will provide a new out-patient anti-GD2 therapeutic option for physicians in the treatment of children facing this advanced form of pediatric cancer. We remain steadfast in our commitment to provide access to DANYELZA and improve the lives of children and families around the globe facing advanced cancers."

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed DANYELZA® (naxitamab-gqgk), which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests in the compound and Y-mAbs.

About DANYELZA® (naxitamab-gqgk)

DANYELZA® (naxitamab-gqgk) is indicated, in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF"), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. This indication was approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a confirmatory trial. DANYELZA® includes a Boxed Warning for serious infusion-related reactions, such as cardiac arrest and anaphylaxis, and neurotoxicity, such as severe neuropathic pain and transverse myelitis. See full Prescribing Information for complete Boxed Warning and other important safety information.

DANYELZA is currently not approved for the treatment of osteosarcoma in any jurisdiction.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, radioimmunotherapy and antibody-based therapeutic cancer products. The Company's technologies include its investigational Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy Platform ("PRIT") and bispecific antibodies generated using the Y-BiClone platform. The Company's broad and advanced product pipeline includes the anti-GD2 therapy DANYELZA® (naxitamab-gqgk), the first FDA-approved treatment for patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow after a partial response, minor response, or stable disease to prior therapy.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, statements about expectations relating to the Company's partnership with Nobelpharma, including the development process and regulatory submissions with respect to the potential approval and commercialization of DANYELZA in Japan and the potential indications thereof; the receipt by the Company of any payments or royalties from Nobelpharma; and other statements that are not historical facts. Words such as ''anticipate,'' ''believe,'' ''contemplate,'' ''continue,'' ''could,'' ''estimate,'' ''expect,'' "hope," ''intend,'' ''may,'' ''might,'' ''plan,'' ''potential,'' ''predict,'' ''project,'' ''should,'' ''target,'' "will," "would',' "guidance," "goal," "objective," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with the Company's reliance on a third-party for development work associated with the regulatory process with respect to and potential commercialization of DANYELZA in Japan; cost and success of the Company's and Nobelpharma's product development activities and clinical trials; the risks of delay in the timing of the Company's and Nobelpharma's regulatory submissions or failure to receive approval of DANYELZA in Japan; and the risks related to commercializing any approved pharmaceutical product in a territory, including with respect to the rate and degree of market acceptance. All statements are subject to the risks described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and the Company's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2024 and June 30, 2024, and future filings and reports by the Company. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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