

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

Current report filing

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### FILER

#### Inmune Bio, Inc.

CIK: [1711754](#) | IRS No.: **475205835** | State of Incorp.: **NV** | Fiscal Year End: **1231**  
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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): February 6, 2025

INMUNE BIO INC.

(Exact name of registrant as specified in charter)

Nevada

(State or other jurisdiction  
of incorporation)

001-38793

(Commission File Number)

47-5205835

(IRS Employer  
Identification No.)

**225 NE Mizner Blvd., Suite 640, Boca Raton, Florida 33432**

(Address of Principal Executive Offices) (Zip Code)

**(858) 964 3720**

(Registrant's Telephone Number, Including Area Code)

**Not Applicable**

(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, par value \$0.001 per shares	INMB	The NASDAQ Stock Market LLC

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. ☐

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**Item 1.01 Entry into a Material Definitive Agreement.**

On February 6, 2025, INmune Bio Inc. (the “Company”) and Great Ormond Street Hospital NHS Foundation Trust (“GOSH”) entered into a license agreement (the “License Agreement”) for the exclusive commercial use to clinical trial data associated with the Mission EB study (the “Mission EB study”) investigating the potential of CORDStrom to treat recessive dystrophic epidermolysis bullosa (“RDEB”) in pediatric patients. The Company owns the intellectual property covering CORDStrom, the investigational medicinal product used in the Mission EB study. In addition, the Company owns intellectual property and maintains trade secret protections covering the manufacturing of CORDStrom.

The Company intends to use the license to prepare applications seeking marketing authorization of CORDStrom for treatment of pediatric RDEB in each of the U.S. Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”) and Medicines and Healthcare Products Regulatory Agency (“MHRA”).

Under the terms of the License Agreement, the Company has agreed to an upfront payment of £250,000 (approximately \$0.3 million) within thirty (30) days of the effective date of the License Agreement and a single milestone payment up to £6,000,000 (approximately \$7.5 million) due on the first marketing authorization to be granted by the FDA, EMA or MHRA. The Company has also agreed to certain patient access obligations, including sponsoring the supply of CORDStrom to United Kingdom patients enrolled in an open label continuation of the Mission EB study.

The term of the License Agreement shall continue in effect ten (10) years. The Company may terminate the License Agreement by delivering sixty (60) days written notice to GOSH upon (i) notice from the FDA, MHRA, or EMA that the results of the Mission EB, are insufficient to support a marketing authorization, or (ii) notice that CORDStrom has been refused authorized for reimbursement by the National Health Service, or (iii) the Company is unable to procure starting materials for manufacturing, or to manufacture CORDStrom within eighteen (18) months of the effective date of the License Agreement, in either case due to regulatory, facility or supply chain events not within the Company’s reasonable control. Either party may terminate the License Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party.

The foregoing description of the material terms of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the License Agreement, a copy of which is filed herewith as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 1.02 Termination of a Material Definitive Agreement.**

On February 6, 2025, the Company and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (“SVB”) entered into a letter agreement pursuant to which the Company and SVB terminated the Loan and Security Agreement (the “Loan Agreement”) dated as of June 10, 2021, by and between the Company, as borrower, and SVB as administrative agent, collateral agent and lender and SVB Innovation Credit Fund VIII, L.P., as a lender, pursuant to a termination letter (the “Termination Letter”).

As of the date of the Termination Letter, no amounts were due or owed by the Company to SVB under the Loan Agreement. No early termination penalty was paid in connection with the Termination Letter.

Pursuant to the Termination Letter and in accordance with the terms of the Loan Agreement, the Company continues to be bound by certain terms under the Loan Agreement that customarily survive the termination of similar agreements, including, without limitation, certain indemnification obligations.

The foregoing description of the Termination Letter is qualified in its entirety by reference to such document, which is filed as Exhibit 10.2 to this Current Report on Form 8-K and is incorporated herein by reference.

## Item 8.01. Other Events.

On February 10, 2025, the Company issued a press release announcing its entry into the License Agreement. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	<a href="#">License Agreement, dated February 6, 2025, between INmune Bio Inc. and Great Ormond Street Hospital for Children NHS Foundation Trust</a>
10.2	<a href="#">Termination Letter, dated February 6, 2025, between INmune Bio Inc. and Silicon Valley Bank, a division of First-Citizens Bank &amp; Trust Company</a>
99.1	<a href="#">Press Release, dated February 10, 2025</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## 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.

### INMUNE BIO INC.

Date: February 10, 2025

By: /s/ David Moss

Name: David Moss

Title: Chief Financial Officer

## LICENSE AGREEMENT

This License Agreement (this “**Agreement**”) is entered into as of the date of last signature below (the “**Effective Date**”), by and between INmune Bio Inc., a corporation formed under laws of the state of Nevada in the United States of America, having a place of business at 225 NE Mizner Blvd., Suite 640, Boca Raton, Florida 33432 (“**Licensee**”) and Great Ormond Street Hospital for Children NHS Foundation Trust, whose registered address is at Great Ormond Street, London, WC1N 3JH (“**Licensor or GOSH**”). Each may be referred to as a “**Party**” and collectively the “**Parties**”.

**WHEREAS**, Licensor owns rights to IP Assets as defined herein;

**WHEREAS**, Licensee is the owner of the CORDStrom product and owns, creates and uses intellectual property related to its CORDStrom product;

**WHEREAS**, Licensee wishes to obtain a license under the IP Assets in order to advance the Purpose as set forth in this Agreement; and

**WHEREAS**, Licensor wishes to grant a license under the IP Assets to Licensee in furtherance of the Purpose and the Licensee has agreed to accept such license, on the terms set out in this Agreement.

**NOW, THEREFORE**, the Parties hereto, intending to be legally bound, hereby agree as follows:

### 1. Definitions.

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1, whether used in the singular or the plural, shall have the meanings specified below.

**1.1. “Affiliate”** means, with respect to a person, organization or entity, any person, organization or entity controlling, controlled by or under common control with, such person, organization or entity. For purposes of this definition, “control” when used with respect to any specified person means the power to direct the management and policies of such person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise and the terms “controlling” and “controlled” have meanings correlative to the foregoing.

**1.2. “Anonymised”** means, in respect of any data, anonymised such that any individual to whom the original data relates cannot be identified or re-identified, directly or indirectly, by or on behalf of the Licensee or any third-party and any way of identifying any individual to whom the original data relates has been irreversibly destroyed.

**1.3. “Confidential Information”** means any technical, business, or other Information provided by or on behalf of one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”) in connection with the subject matter of this Agreement, whether prior to, on, or after the Effective Date. Confidential Information of a Disclosing Party shall include all information and materials disclosed by such Disclosing Party that (a) is marked as “Confidential,” “Proprietary,” or with similar designation at the time of disclosure, or (b) by its nature would reasonably be expected by the Receiving Party to be considered Confidential Information. Information disclosed orally shall not be required to be identified as such to be considered Confidential Information. As used herein, “Confidential Information” shall not include any information that:

(a) is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

(b) can be demonstrated by documentation or other competent proof to have been in the receiving Party’s possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

(c) is subsequently received by the receiving Party from a third Party who is not bound by any obligation of confidentiality with respect to such information;

(d) has been published by a third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement; or

(e) can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to, use of or knowledge of the disclosing Party's Confidential Information.

**1.4. "CORDStrom"** means Licensee's medical product comprising aseptic, allogeneic, pooled, human umbilical cord -derived mesenchymal stromal cells (hucMSCs) in suspension for infusion or intravenous injection.

**1.5. "Diligent Efforts"** means the carrying out by the Licensee of obligations or tasks in a sustained manner consistent with the commercially reasonable efforts that the Licensor and its Affiliates devote to a research, development or marketing project for a pharmaceutical product or products of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing.

**1.6. "IP Assets"** means the MissionEB Data together with any MissionEB Extended Data as defined herein. For clarity, all IP Assets shall be made available to Licensee in de-identified anonymous format only.

**1.7. "MissionEB Data"** means any research and clinical data in the possession and control of Licensor which was collected or derived from the MissionEB Study as described in the MissionEB Study protocol on or prior to the Effective Date, including clinical study data, raw data (though raw data will not be provided directly to Licensee but will be analysed by an independent statistician in accordance with Clause 3.1 and the results of the data analysis reported to the Licensee), analysis datasets, and specifications, original source data, images and case report forms, collected or generated with respect to the MissionEB Study (each in Anonymised format only), together with all analysis, reports, and results with respect thereto, in the possession and control of the Licensor. The MissionEB Data includes data from Part 1 of the MissionEB Study, which is completed.

**1.8. "MissionEB Extended Data"** means any further research and clinical data, not MissionEB Data, that may arise from the open label element of the MissionEB Study and any other study forming part of the MissionEB Study (each in Anonymised format only), and which is in the possession and control of the Licensor.

**1.9. "MissionEB Study"** means the study investigating the potential of CORDStrom to treat recessive dystrophic epidermolysis bullosa (RDEB) in pediatric patients, titled "Mesenchymal stromal cell therapy for children with recessive dystrophic epidermolysis bullosa," as identified by ISRCTN No.: [ISRCTN14409785](https://doi.org/10.1186/ISRCTN14409785), EudraCT/CTIS No.: 2020-005049-18, IRAS No.: 281748, and DOI: <https://doi.org/10.1186/ISRCTN14409785>.

**1.10. "Purpose"** as used herein means development of CORDStrom and seeking marketing authorisations (in the US, UK and Europe) for the use of CORDStrom for the treatment of epidermolysis bullosa (EB), and more particularly, recessive dystrophic epidermolysis bullosa (RDEB) in pediatric patients and such other purposes as may be agreed between the Parties from time to time.

**1.11. "Territory"** shall be worldwide.

## **2. License Grant.**

**2.1. License.** In consideration of the payments to be made by Licensee to Licensor pursuant to Section 4 of this Agreement and subject to the terms and conditions set forth in this Agreement, Licensor hereby grants to Licensee an exclusive, worldwide, sub-licensable license under the IP Assets in furtherance of the Purpose, which license shall be sub-licensable in accordance with Section 2.2. Such license shall include, without limitation, access to the IP Assets necessary to develop and submit an application for marketing authorization seeking approval of CORDStrom from each of the United States Food & Drug Administration ("FDA"), the United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA"), and the European Medicines Agency ("EMA") in an indication related to the Purpose.

**2.2. Sublicense.** The license granted in Section 2.1. may be sublicensed by Licensee to any Affiliate or third Party provided that prior to Licensee entering into any sublicense with a non-Affiliate third party it must obtain written approval from Licensors, which approval will not be unreasonably withheld or delayed. Any such sublicense shall be in writing, and shall be consistent with and subject to the terms of this Agreement and shall include all obligations of Licensee in no less stringent terms than those set forth herein. The Licensors shall be an express third-party beneficiary of any such sublicense and such sublicenses shall not include the right to grant further sublicenses and shall be co-terminous with this Agreement. The Licensee shall be responsible for any breach of this Agreement that is caused (directly or indirectly) by the performance (or failure to perform) of any of its sublicensees.

**2.3. Reservation of Rights.** Licensors reserves all other rights not expressly licensed to Licensee herein, including the right to use the IP Assets for any research, training, teaching or other non-commercial purpose and for the care and treatment of pediatric patients with RDEB.

### **3. Licensors's Obligations.**

**3.1.** Licensors shall provide the IP Assets to Licensee other than any raw data. The Licensors shall appoint an independent statistician (in consultation with the Licensee) and will provide the raw data to such statistician and shall request its collaborating statisticians at Sheffield University under the MissionEB Study to do the same). The independent statistician will (at the cost of the Licensors) perform the analysis of the raw data in order for such raw data to be in the form required to support an application for marketing authorization seeking approval of CORDStrom from each of the FDA, the MHRA and the EMA in an indication related to the Purpose and will provide the results of such analysis to the Licensee, in de-identified and anonymized form. Prior to providing the IP Assets to the Licensee as above, the Parties shall first execute a separate Data Transfer Agreement, which Data Transfer Agreement shall specify terms related to data security and control for transfer and management of the IP Assets.

**3.2.** Licensors shall, at the cost of the Licensee, make its research team available to Licensee for activities related to advancing the Purpose, including presenting the MissionEB Data upon reasonable request and with sufficient notice, for example, in a key opinion leader presentation or a presentation in support of regulatory meetings.

**3.3.** To the extent required to facilitate a marketing authorization in the FDA and subject to agreement between the Parties as to payment of the costs of doing so, Licensors shall cooperate with Licensee to open one or more US-based sites for treating similar patients in the United States under the MissionEB Study protocol, Part 2, or otherwise as necessitated by an amendment to such study protocol. For clarity, Licensors's obligations under this Section 3.3. shall be limited to non-financial cooperation, such as, without limitation, facilitating protocol amendment(s) and Licensors's independent submissions in the US FDA.

### **4. Licensee's Obligations.**

#### **4.1 General.** Licensee shall:

**4.1.1.** take all Diligent Efforts necessary to successfully manufacture CORDStrom and market in the Territory, including seeking a regulatory marketing authorization and approval of CORDStrom for use in the treatment of RDEB in pediatric patients from each of the FDA, MHRA, and EMA;

**4.1.2.** satisfy the patient access obligations in Section 4.2; and

**4.1.3.** satisfy the financial obligations in Section 4.3.

**4.1.4.** Notwithstanding anything else herein, Licensee shall have the ability, at its sole discretion but no obligation, to contribute additional financial and/or other resources to the further clinical development of the MissionEB Data.

**4.2 Patient Access.** Licensee shall supply Licensors an amount of CORDStrom sufficient to carry out clinical research and to treat all pediatric patients with RDEB managed at GOSH and associated clinical sites, provided such pediatric patients are enrolled in the MissionEB Study in UK, including an open label extension and any amendments or extensions thereto, such supply of CORDStrom shall be at no cost to Licensors until:

**4.2.1.** completion or termination of the MissionEB Study; or

**4.2.2.a.** receipt of grant of MHRA marketing authorization for CORDStrom for the treatment of RDEB in pediatric patients in the UK, and

**4.2.2.b.** the use of CORDStrom for the treatment of pediatric patients in the UK has been approved by the National Institute for Health and Care Excellence (NICE) under its technology appraisal process, and

**4.2.2.c.** the National Health Service (NHS) has approved the re-imbursement of the CORDStrom product to treat pediatric patients with RDEB in England (which approval is generally granted within 90 days from publication of the NICE technology appraisal.

**4.3 Financial.** In consideration of the rights granted under this Agreement, Licensee shall pay to Licensor:

**4.3.1.** an initial payment of £250,000, to be paid in full within thirty (30) days of the Effective Date;

**4.3.2.** the amount of £ 6,000,000 as a single milestone payment, such payment due in full within 30 days on the first to occur of Licensee (or an Affiliate) receiving the first-to-occur biologics licence application (BLA) approval or equivalent marketing authorization from one of: the FDA, MHRA, or EMA, which approval or authorization licenses the sale of CORDStrom for the treatment of RDEB in pediatric patients (“**Approval**”).

**4.3.3.** Unless a delay is caused by Licensee’s failure to timely provide access to CORDStrom IMP under Section 4.2. herein, if the open label Part 2 of the MissionEB Study is not initiated with a first patient dosed by 31 December 2025, the single milestone payment shall be reduced to £ 4,800,000.

**4.3.4.** These obligations under Section 4.3 shall constitute the sole financial obligation of Licensee under this Agreement save in respect of other payments to be agreed (for example pursuant to Section 3.3).

**4.3.5.** Each such payment shall be net of any taxes or other deductions, withholdings or charges.

**4.4.** The Licensee shall, and shall procure that its Affiliates or sublicensees shall not do, or omit to do, anything which could reasonably be expected to diminish the rights of the Licensor in the IP Assets, it being understood and acknowledged that the Licensee’s exercise of its rights granted under this Agreement in accordance with its terms shall not be considered to diminish such rights.

**4.5.** The Licensee shall keep and maintain complete, true, and accurate records in sufficient detail to enable its compliance with the terms of this Agreement to be assessed. The Licensee shall retain such records for at least five (5) years after the date of expiry or termination of this Agreement and make such records open for inspection by the Licensor during the term of this Agreement and for five years thereafter in order to allow the assessment of Licensee’s compliance with the terms of this Agreement.

## **5. Confidentiality & Publication.**

**5.1. Confidential Information.** Each Party shall maintain all Confidential Information of the other Party in confidence and shall not disclose any such Confidential Information to any third party, except as expressly provided herein, or use any such confidential Information for any purposes other than those necessary or permitted for performance under this Agreement. No Party shall disclose Confidential Information of the other Party to any employee, agent, consultant, Affiliate, or sublicensee who does not have a reasonable need for such Information and who is not subject to binding obligations of confidentiality and limited use at least as restrictive in scope as those of this Article 5 (but may disclose to those that have such a reasonable need and are so bound). The duration of such obligations of confidentiality under this Section shall survive the expiration or termination of this Agreement and shall remain in effect for five (5) years after any such expiration or termination. Each Party shall use at least the same standard of care as it uses to protect its own Confidential Information of a similar nature to prevent unauthorized disclosures or uses of Confidential Information of the other Party. Each Party shall promptly notify the other Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

**5.2. Authorized Disclosure.** Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information of the other Party only to the extent that any such disclosure is necessary:

**5.2.1.** to the extent and to the persons and entities required by an applicable governmental law, rule, regulation or order; provided, however, that the responding Party shall first have given prompt notice to the other Party hereto to enable it to



seek any available exemptions from or limitations on such disclosure requirement and shall reasonably cooperate in such efforts by the other Party;

**5.2.2.** to the extent and to the persons and entities required by rules of other securities regulators, or exchanges on which such Party's stock is listed; or

**5.2.3.** to prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement,

**5.2.4.** to discuss with bona fide potential (and actual) corporate partners or licensees, potential (and actual) investors or merger or acquisition partners, and to financial underwriters and legal and financial advisors, provided that all such disclosures shall be made only to such Parties under binding written obligations of confidentiality and non-use consistent with the provisions of this Article 5, or

**5.2.5.** to further the Purpose by sharing Confidential Information with a regulatory agency, including, without limitation, the FDA, EMA, and MHRA.

**5.2.5.** To facilitate a minimum accepted disclosure intended for public dissemination and satisfaction of Licensee's obligations as a public company and/or the Licensor's obligations as a UK public body, the Parties expressly agree that the information contained in Appendix 1 "Authorized Disclosures" as attached herewith shall be deemed non-confidential information after the Effective Date and available for publication by Licensee in a public facing press release and/or a filing with the United States Securities Exchange Commission (SEC) or to a UK regulatory authority.

**5.3. Return of Confidential Information.** Upon expiration of the Agreement or if this Agreement is terminated., the Party in receipt of Confidential Information will, at the other Party's option, either promptly return, or destroy and certify that it has destroyed, all copies, in its or any of its representatives' possession or control, of any and all documents, computer files and other materials that contain or are derived from any Confidential Information. Each Party will be allowed to keep one archival copy of the other Party's Confidential Information for record-keeping purposes only, but shall destroy such Confidential Information prior to expiration of the confidentiality obligations hereunder.

**5.4. Use of Names, Logos or Symbols.** Other than legally required disclosures and disclosures required by the rules of any securities exchange on which a disclosing Party's stock is (at the time) traded (of which advance notice and discussion to the full extent reasonably practicable shall be provided, but for which a Party shall not be required to obtain consent from the other Party), neither Party shall use the name, trademarks, logos, physical likeness, employee names or owner symbol of the other Party for any publicity, promotion or similar public use without the prior written consent of the affected Party. Unless expressly stated herein, nothing in this Agreement shall be construed as granting either Party any rights or license to use any of the other Party's trademarks or trade names without separate, express prior written permission of the owner of such trademark or trade name.

**5.5. Scientific Presentation & Publication.** As well as expressly authorized in Section 5.2.5., Licensor reserves a right to first publish the MissionEB Data in an academic or scientific journal of its sole and exclusive choice, or to present at a professional scientific or medical meeting. Upon receiving notice of acceptance for publication, Licensor shall share a copy of such publication with Licensee.

## **6. Term & Termination.**

**6.1. Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article 6, shall continue in full force until its expiration occurring on the date that is ten (10) years from the Effective Date (the "Term").

### **6.2. Termination.**

**6.2.1. Termination Without Cause.** Licensee may terminate this Agreement (in whole or in part with respect to a particular territory) upon sixty (60) days' prior written notice to Licensor subject to the occurrence of any of the following events:

**6.2.1.1.** Licensee receives notice from the FDA, MHRA, or EMA that the IP Assets, alone and without further clinical development of the MissionEB Data, are insufficient to support a marketing authorization.

**6.2.1.2.** Licensee receives notice from NICE that CORDStrom has been refused authorized for NHS reimbursement.

**6.2.1.3.** having made Diligent Efforts to do so, Licensee is unable to procure starting materials for manufacturing, or to manufacture CORDStrom within eighteen months of the Effective Date, in either case due to regulatory, facility or supply chain events not within Licensee's reasonable control.

**6.2.2. Termination for Default.**

**6.2.2.1.** In the event that either Party commits a material breach of its obligations under this Agreement and, if such breach is capable of remedy, fails to cure that breach within thirty (30) days after receiving written notice thereof, the other Party may terminate this Agreement immediately upon written notice to the Party in breach.

**6.2.2.2.** The occurrence of any of the following events (by way of example and without limitation) shall constitute a material breach of this Agreement by Licensee:

**6.2.2.2.1.** failure of Licensee to file an application seeking marketing authorization of CORDStrom for treatment of RDEB in pediatric patients from one of the FDA, MHRA, or EMA within twenty four months from the Effective Date;

**6.2.2.2.2.** failure of Licensee to obtain a marketing authorization of CORDStrom for treatment of RDEB in pediatric patients from one of the FDA, MHRA, or EMA within four (4) years from the Effective Date of this Agreement.

**6.2.2.3.** On the occurrence of an event described in Section 6.2.1.1., the obligations under subparts 6.2.2.2.1. and 6.2.2.2.2. shall have the effect of being deleted and no longer in force.

**6.2.3. Bankruptcy.** Licensor may terminate this Agreement upon notice to Licensee if Licensee becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against Licensee and not dismissed within ninety (90) days, or if the Licensee becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business or an equivalent event occurs in any other jurisdiction.

**6.3. Effect of Termination or Expiration.**

**6.3.1. Termination of Rights.** Upon expiration or termination of this Agreement by either Party pursuant to any of the provisions of Section 6.2. the rights and licenses granted to Licensee under Section 2 shall terminate, all rights in and to and under the IP Assets will revert to Licensor and neither Licensee nor its Affiliates may make any further use or exploitation of the IP Assets. Each Party shall return to the other Party or destroy (and certify such destruction to such other Party) all Confidential Information of the other Party; provided, that each Party shall be entitled to retain one (1) copy solely for archival and compliance purposes to the extent required by applicable law.

**6.3.2. Accruing Obligations.** Termination or expiration of this Agreement shall not relieve Licensee of its obligations arising under Section 4.2 or 4.3, if Licensee, subsequent to termination or expiration, obtains a marketing authorization from the FDA, MHRA, or EMA to market CORDStrom for RDEB provided the IP Assets were used by Licensee and contributed to the award of such marketing authorization.

**6.4. Survival.** The Parties' respective rights, obligations and duties under Sections 5, 6.3., 7, 8, 9, and 10, as well as any rights, obligations and duties which by their nature or as expressly stated herein shall extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement.

## **7. Warranties; Limitation of Liability.**

**7.1. Compliance with Law.** Licensee represents and warrants that it will comply, and will ensure that its Affiliates comply, with all local, state, federal and international laws and regulations relating to use of the IP Assets.

### **7.2. No Warranty.**

**7.2.1.** NOTHING CONTAINED HEREIN SHALL BE DEEMED TO BE A WARRANTY BY LICENSOR THAT ANY OF THE IP ASSETS WILL SATISFY THE CLINICAL REQUIREMENTS FOR RECEIVING MARKETING AUTHORIZATION OF CORDSTROM FOR TREATMENT OF RDEB IN ANY JURISDICTION.

**7.2.2.** LICENSOR MAKES NO WARRANTIES WHATSOEVER AS TO THE COMMERCIAL OR SCIENTIFIC VALUE OF THE IP ASSETS.

**7.2.3.** EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

**7.3. Limitation of Liability.** Except with respect to matters for which Licensee is obligated to indemnify Licensor under Section 8, neither Party will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for: (a) any indirect, incidental, consequential or punitive damages or lost profits, or (b) cost of procurement of substitute goods, technology or services.

## **8. Indemnification and Insurance.**

### **8.1. Indemnity.**

**8.1.1.** Licensee shall indemnify, defend and hold harmless Licensor and its current and former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees and agents and their respective successors, heirs and assigns (the "Indemnitees") from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature based upon, arising out of or otherwise relating to this Agreement, including any cause of action relating to product liability concerning any product, process or service made, used, sold or performed pursuant to any right or license granted under this Agreement (collectively "Claims"). Neither Licensee nor Licensor shall settle any Claim without the prior written consent of the other, which consent shall not be unreasonably withheld.

**8.1.2.** Licensee shall, at its own expense, provide attorneys reasonably acceptable to Licensor to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

### **8.2. Insurance.**

**8.2.1.** Beginning on the Effective Date, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$5,000,000 per incident and \$5,000,000 annual aggregate. In the event of clinical trials occurring in the United States in furtherance of Section 3.3., Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as Licensor shall require. Such commercial general liability insurance shall provide (a) product liability coverage and (b) broad form contractual liability coverage for Licensee's indemnification obligations under this Agreement.

**8.2.2.** Licensee shall provide Licensor with written evidence of such insurance upon request of Licensor. Licensee shall provide Licensor with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance.

## 9. Dispute Resolution.

**9.1.** The Parties recognize that disputes may from time to time arise between the Parties during the term of this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and prior to resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 9 to resolve any dispute arising under this Agreement.

**9.2.** Upon the request of either Party, the Parties agree to meet and discuss in good faith a possible resolution of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, which good faith efforts shall include at least one in-person (including video conference, camera and mic active) meeting between the senior management of each Party.

## 10. Miscellaneous.

**10.1. Entire Agreement.** This Agreement is the sole agreement with respect to the subject matter hereof and, except as expressly set forth herein, supersedes all other agreements and understandings between the Parties with respect to the subject matter hereof.

**10.2. Notices.** Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by electronic mail (email), courier or certified mail, return receipt requested, to the following addresses, unless the Parties are subsequently notified of any change of address in accordance with this Section 10.3:

If to Licensee:

Attn.: Legal  
 Email: legal@immunebio.com  
 Physical: INmune Bio Inc.  
 225 NE Mizner Blvd., Suite 640  
 Boca Raton, FL 33432 USA

If to Licensor:

Attn.: Dr Vanshree Patel  
 Email: research.governance@gosh.nhs.uk  
 quoting ref: MissionEB  
 Physical: Great Ormond Street Hospital for Children NHS Foundation Trust  
 Great Ormond Street, London, WC1N 3JH UK

Any notice shall be deemed to have been received as follows: (a) by personal delivery or expedited delivery, upon receipt; (b) by email upon dispatch; (c) by certified mail, as evidenced by the return receipt. If notice is sent by email, a confirming copy of the same shall be sent by mail to the address for notice.

**10.3. Governing Law and Jurisdiction.** This Agreement and any obligations arising out of or in connection with it shall be governed by the laws of England and Wales; the Parties submit to the jurisdiction of the English Courts to determine any dispute arising out of or in connection with the Agreement.

**10.4. Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

**10.5. Headings.** Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

**10.6. Counterparts.** The Parties may execute this Agreement in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. Transmission by electronic mail of an executed

counterpart of this Agreement shall be deemed to constitute due and sufficient delivery of such counterpart. If by electronic mail, the executed Agreement must be delivered in a .pdf format.

**10.7. Amendment; Waiver.** This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party waiving compliance. The delay or failure of either Party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

**10.8. No Agency or Partnership.** Nothing contained in this Agreement shall give either Party the right to bind the other, or be deemed to constitute either Party as agent for or partner of the other or any third Party.

**10.9. Assignment and Successors.** This Agreement may not be assigned by either Party without the consent of the other, which consent shall not be unreasonably withheld, except that each Party may, without such consent, assign this Agreement and the rights, obligations and interests of such Party to any of its Affiliates, to any purchaser of all or substantially all of its assets to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation; provided, in each case, that the assignee agrees in writing to be bound by the terms of this Agreement. Any assignment purported or attempted to be made in violation of the terms of this Section 10.9 shall be null and void and of no legal effect.

**10.10. Force Majeure.** Except for monetary obligations hereunder, neither Party will be responsible for delays resulting from causes beyond the reasonable control of such Party, including fire, explosion, flood, pandemic, war, strike, or riot, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

**10.11. Interpretation.** Each Party hereto acknowledges and agrees that: (a) it and/or its counsel reviewed and negotiated the terms and provisions of this Agreement and has contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; (c) the terms and provisions of this Agreement shall be construed fairly as to both Parties hereto and not in favor of or against either Party, regardless of which Party was generally responsible for the preparation of this Agreement and (d) the use of "include," "includes," or "including" herein shall not be limiting and "or" shall not be exclusive.

**10.12. Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of this Agreement shall not be affected.

**IN WITNESS WHEREOF,** the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Licensor:

Licensee:

Great Ormond Street Hospital for Children NHS Foundation Trust

INmune Bio Inc.

/s/ Margaret Monckton

/s/ R.J. Tesi, CEO

Margaret Monckton

R.J. Tesi, CEO

02/06/2025

02/06/2025

Date

Date

## Appendix 1

### Authorized Disclosures

1. INmune Bio Inc. (“INmune”) and Great Ormond Street Hospital for Children NHS Foundation Trust (“GOSH”) enter into license agreement.
2. As part of the license agreement:
  - a. INmune receives exclusive, global license granting access and use MissionEB Data for development and seeking marketing authorization of CORDStrom for treatment of RDEB in pediatric patients;
  - b. GOSH receives a supply of CORDStrom for treating all patients with RDEB and enrolled in MissionEB study in UK, including an open label extension, which, unless paid for by NIHR is supplied by INmune at no cost to GOSH;
  - c. GOSH also receives (a) an initial payment within thirty (30) days of the Effective Date; and (b) a single milestone payment payable upon first to occur marketing authorization in EMA, FDA, MHRA.
3. Public information:
  - a. Description of MissionEB Study available at <https://www.sheffield.ac.uk/ctru/current-trials/missioneb>
  - b. Study Protocol available at: <https://fundingawards.nihr.ac.uk/award/NIHR127963>
  - c. Study details: <https://www.isrctn.com/ISRCTN14409785>
4. Summary of MissionEB Data:
  - a. Part 1: Randomized placebo controlled double blinded crossover trial with internal phase I dose de-escalation arm
    - i. Dose de-escalation trial was conducted on the first 9 participants at GOSH
    - ii. All participants were randomized to receive two consecutive intravenous MSCs or placebo infusions at day 0 & day 14 and were crossed over to receive the opposite at 9 months & 14 days later
    - iii. Assessed safety of CORDStrom  $3 \times 10^6$ /kg in pediatric patients with RDEB
    - iv. First patient recruited October 2021
    - v. phase I dose de-escalation arm was completed with no toxicity events
    - vi. 37 patients were recruited, 6 patients withdrew (3 investigator decision, 3 patient decision), 1 patient died of complications of RDEB, unrelated to CORDStrom
    - vii. all infusions have been completed (124 infusions given in total)
    - viii. Beneficial effects across all 30 patients receiving CORDStrom were observed for Itch Man Scale, iscorEB clinician score and iscorEB skin involvement
    - ix. Approx. 20% itch reduction
    - x. < age 10

1. Mild improvement in iscorEB clinician score
2. 8.4% improvement in iscorEB skin involvement section statistically significant
3. Itch Man Scale showed a large effect with 20.2% improvement

xi. > age 10

1. Clinically relevant pain reduction in FACES (patient assessment) and VAS (parent assessment) pain scales, -8.3% & 7.3% average pain reduction respectively, -2.8% & 12.5% worst pain reduction respectively

xii. RDEB intermediate

1. greatest and most consistent effects were observed in this of group
2. Large effects for iscorEB clinician score 6% & iscorEB skin 9.1% in favour of treatment, IscorEB skin again statistically significant
3. Mild improvement seen in EBDASI activity score 4% and EBDASI skin score
4. Clinically relevant beneficial effects in pain and itch reduction, -average pain in FACES (patient) improved by 22.2% and worst pain by 27.8%, average pain in VAS (parent) improved by 0.7% and worst pain by 19.1%, 16.4% itch reduction in Itch Man Scale
5. Independent photography reviewers concurred the benefit of CORDStrom in this cohort

xiii. RDEB severe

1. This cohort saw the largest impact in their itch with 23.7% reduction

xiv. Adverse Events

1. 211 Adverse Events (AEs), 109 on CORDStrom, 102 on placebo
2. 22 minor AEs related to infusions, 13 possibly related to CORDStrom, 9 possibly related to placebo

xv. Serious Adverse Events

1. after 124 infusions no serious adverse events (SAEs) were related to CORDStrom or placebo

xvi. 30 SAEs were reported, 16 with CORDStrom, 14 with placebo, none related to the treatment

xvii. 9 AEs related to infusions were categorized as nervous system disorders (headache and dizziness) 8/9 had CORDStrom

xviii. Conclusions

1. There was no safety signal through the study
2. Treatment was well tolerated
3. Beneficial effects across all patients on receiving UC-MSCs were observed for Itch Man Scale, iscorEB clinician score and iscorEB skin involvement

4. Under the age of 10 patients including severe and intermediate showed mild improvement in iscorEB clinician and skin involvement scores. Itch Man Scale had a large response with approximately 20% improvement

5. Intermediate patients saw the largest benefits with improvements seen in
  - a. EBDASI activity score
  - b. EBDASI skin score
  - c. iscorEB clinician score
  - d. iscorEB skin involvement approximately 10%
  - e. Pain score and itch score were reduced by approximately 20% and 15% respectively
6. Patients over the age of 10 saw a reduction in their four pain scales but not in their skin. We had insufficient data to evaluate itch scores
7. Severe patients across all ages did not show improvement in their skin assessments at 3 months. However CORDStrom had the largest impact on their itch with approximately 25% reduction
8. Qualitative interviews showed positive effects in favour of treatment overall. Larger benefits were reported in intermediate and under 10 children
9. There is consistency between the qualitative and quantitative study findings
10. Results of the blinded qualitative analysis and clinical photography were also consistent with these findings
11. Early treatment with CORDStrom infusion in RDEB patients is disease-modifying particularly showing benefits in younger patients with milder disease
12. Severe patients saw a clinically significant improvement in itch. This reduction in itch over time will likely lead to an improvement in wound closure and therefore reduce risk of squamous cell carcinoma in later life
13. Additional 6 months follow-up data as follows:
  - a. Overall improvement of outcome measures were seen with largest effects seen in the younger and intermediate patients
  - b. Itch reduction is maintained 6 months post cell infusions across all of the itch-man scale cohort
  - c. The largest itch reduction was seen in the RDEB-S group at month 6 post cell infusion of 27.5%
  - d. With itch reduction over time IscorEB scores have also improved in both RDEB severe cohort and intermediate
  - e. There is large improvement in iscorEB scores in RDEB-S cohort not seen at month-3 with improvement in overall, patient, clinician and skin score by 9.3%, 9.6%, 6.4% and 2.8% respectively
  - f. The observed skin improvement and wound closure is likely to be disease modifying, improving pain and quality of life and reducing the long-term risk of squamous cell carcinoma







February 6, 2025

INmune Bio, Inc.  
225 NE Mizner Blvd., Ste. 640  
Boca Raton, FL 33432  
Attn:

Re: Termination Letter

Dear David Moss:

We refer to the Loan and Security Agreement dated as of June 10, 2021 (as the same may from time to time have been amended, restated, or otherwise modified, the "Loan Agreement") by and between INmune Bio, Inc. ("Borrower") and SILICON VALLEY BANK, a division of First-Citizens Bank & Trust Company ("SVB" or "Bank"), in its capacity as administrative agent and collateral agent ("Agent"), (b) SVB, as a lender, (c) SVB INNOVATION CREDIT FUND VIII, L.P., ("SVB Capital"), as a lender (SVB and SVB Capital and each of the other "Lenders" from time to time a party hereto are referred to herein collectively as the "Lenders" and each individually as a "Lender"), Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement.

Borrower has advised Bank that Borrower (a) would like to terminate the Loan Agreement, and (b) has waived the right to seek any additional credit extensions, and Bank shall not be obligated to make, and Bank shall not make, any further credit extensions or other financial accommodations under the Loan Agreement to or for the benefit of Borrower.

As of the date hereof, Bank confirms to Borrower that no amounts are due and/or owing by Borrower to Bank under the Loan Documents (as defined below) for any principal, interest, or other amounts (such amounts, collectively, the "Obligations").

Effective immediately upon the execution of this letter by Bank and Borrower (the "Effective Date"), without further action on the part of the parties hereto (i) all Obligations under the Loan Agreement and any other related loan and collateral security documents that may have been issued by Borrower to Bank in connection with the transaction evidenced by the Loan Agreement (collectively, the "Loan Documents"; provided, however, "Loan Documents" shall not include any Bank Services Agreement (as defined below) or any warrant executed by Borrower in favor of Bank or SVB Capital, shall be deemed paid and discharged in full; (ii) all unfunded commitments to make credit extensions or financial accommodations to Borrower or any other person under the Loan Agreement shall be terminated; (iii) all security interests and other liens of every type at any time granted to or held by Bank as security for the Obligations shall be terminated and automatically released without further action by Bank; (iv) all guaranties supporting the Loan Agreement shall be released without further action by Bank; and (v) all other obligations of Borrower shall be deemed terminated; provided, however, those obligations, liabilities, covenants, and terms that are expressly specified in any Loan Document as surviving that respective agreement's termination, including without limitation, Borrower's indemnity obligations set forth in the Loan Agreement, shall continue to survive notwithstanding this termination.

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Bank authorizes Borrower, or any other party on behalf of Borrower, upon or after the Effective Date, to prepare and file any UCC-3 Termination Statements or other documents necessary to evidence the release of Bank's security interests in any of Borrower's property or assets that secured the Obligations and in any third party and any of such third party's property or assets that guarantied the Obligations or provided collateral security therefore. Within three (3) business days following the Effective Date, Bank shall (i) if required by any third party, deliver to such third party such termination notices relating to any deposit or securities account control

agreements or other notices terminating Bank's security interest arising under the Loan Documents, and (ii) if applicable, return any pledged stock in Bank's possession to the pledgor; provided, that any costs or expenses incurred by Bank with respect to such items (including all reasonable attorneys' fees and expenses) shall be reimbursed promptly by Borrower on demand. From and after the Effective Date, Bank further agrees to procure, deliver, or execute and deliver to Borrower, from time to time, all further releases not specified above, certificates, instruments, and documents as may be reasonably requested by Borrower or which are required to evidence the consummation of the payoff contemplated hereby, in each case at the expense of Borrower (including all reasonable attorneys' fees and expenses).

This letter may be executed by any of the parties hereto on separate counterparts, and all of said counterparts taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this letter by facsimile or other electronic transmission shall be effective as delivery of a manually executed counterpart hereof.

This letter shall be governed by the laws of the State of California and shall become effective only when signed by Bank and accepted by Borrower by its due execution in the space provided below.

Very truly yours,

FIRST CITIZENS BANK & TRUST

By: /s/ Kristine Rohmer

Name: Kristine Rohmer

Title: Managing Director

Acknowledged by:

INMUNE BIO, INC.

By: /s/ David Moss

Name: David Moss

Title: CFO

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2

Exhibit A

Bank Services Agreements

- 1) Credit Card Agreement by and between SVB and INmune Bio, Inc.

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3



**INmune Bio Announces Plan to Submit FDA Biologics License Application (BLA) Seeking Approval of CORDStrom for Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB)**

- *The Company reports results of a double-blinded, randomized, placebo-controlled study, known as “MissionEB,” investigating CORDStrom for treatment of RDEB in pediatric patients, which evidence a favorable benefit-risk profile in support of the intended applications for marketing authorization.*
- *CORDStrom, developed by INmune Bio is a patent pending, off the shelf, advanced mesenchymal stromal cell (MSC) platform developed to treat complex inflammatory diseases that has significant clinical development advantages over current MSC products.*
- *FDA grants CORDStrom a Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) for treatment of epidermolysis bullosa (EB).*
- *Parallel efforts will seek marketing authorizations in the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).*
- *Investor Webcast Today at 8:30 a.m. ET.*

**Boca Raton, Florida, Feb. 10, 2025 (GLOBE NEWSWIRE) -- INmune Bio, Inc. (NASDAQ: INMB) (the “Company”),** a clinical-stage inflammation and immunology company focused on developing treatments that harness the patient’s innate immune system to fight disease, announced today, following a Type C meeting with the U.S. Food and Drug Administration (FDA), its intent to submit a BLA in the US and Marketing Authorization Application (MAA) in the UK and EU supported by data from the MissionEB clinical trial investigating CORDStrom as a disease-modifying therapy for treating RDEB in pediatric patients.

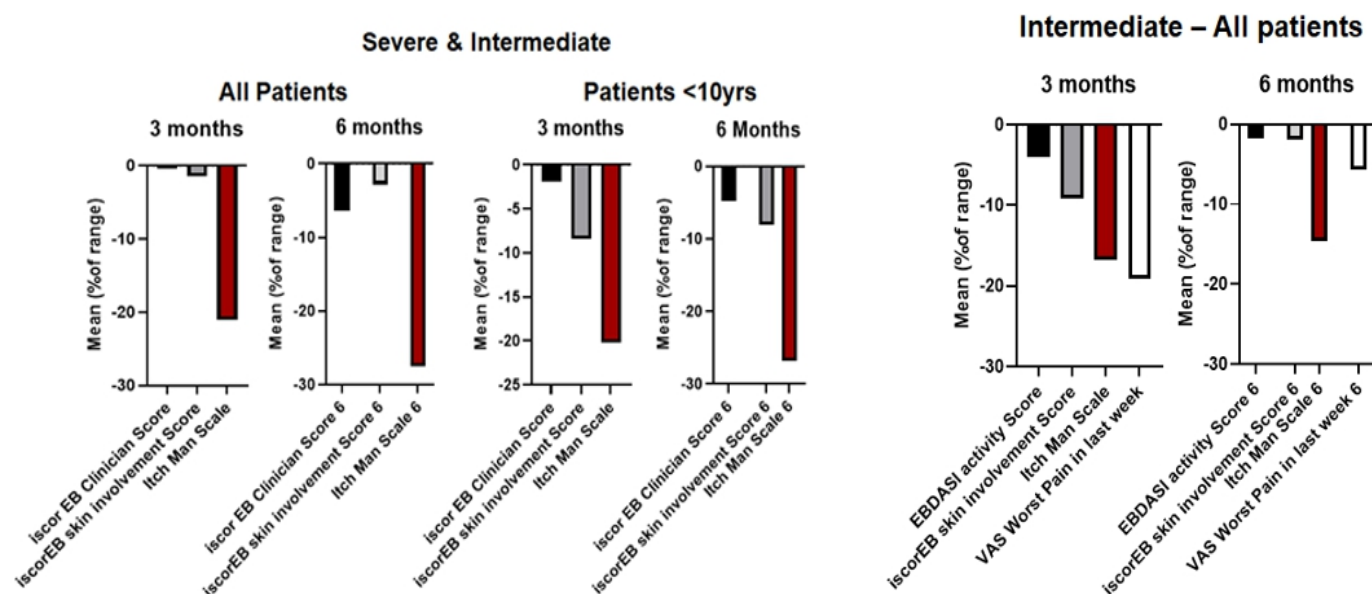
RDEB is a rare, severely debilitating genetic disease, which has its onset in early childhood. Patients’ skin is extremely fragile and is easily damaged, resulting in painful and itchy blistering wounds and scarring that can lead to aggressive and life-threatening skin cancer in adulthood. Long-term morbidity is driven by a debilitating itch and pain that significantly exacerbates wounds and deeply affects quality of life. The currently available treatments target active lesions via topical administration and have a limited benefit. The Company estimates roughly 4,500 children with intermediate or severe RDEB in the US, UK and EU may benefit from systemic CORDStrom therapy (all RDEB incidence: 95 per million live births, at least ~37% of all RDEB are RDEB intermediate or severe), which represents a large unmet opportunity to potentially provide routine clinical care to these children via systemic treatment.

The MissionEB study, led by Dr. Anna Martinez and team at the Great Ormond Street Hospital (GOSH) in collaboration with clinicians from Birmingham’s Children’s Hospital, was a double blind, placebo-controlled, cross-over study evaluating the safety and efficacy of CORDStrom in 30 pediatric patients (age <16 years) in the UK with intermediate or severe RDEB. Subjects were randomized to CORDStrom or placebo and received two intravenous infusions two weeks apart. Half of the patients were treated with CORDStrom and then crossed over to Placebo following a washout period and the other half were treated with Placebo and then crossed over to CORDStrom. Efficacy was assessed at 3- and 6-months from the first infusion per study arm. Thus, all patients are included in the 3- and 6-month efficacy assessment of both placebo and CORDStrom.

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CORDStrom was extremely well tolerated, with no serious adverse events related to CORDStrom reported at either 3-months or 6-months post-treatment across all age and RDEB-severity patient sub-types. In children with severe disease, CORDStrom reduced itch

at 3-months and led to a sustained reduction of over 27% at 6-months. These results demonstrate that a clinically meaningful reduction in itch severity is sustained over time. In children with intermediate disease severity, CORDStrom provided a broader range of improvements, including reduced skin involvement and less pain, as well as a large reduction in itch. In younger children with RDEB (age <10yrs), CORDStrom provided improvements in skin scores, indicating better skin integrity and reduced disease activity. Interviews with subjects and caregivers strongly support the clinical benefits of CORDStrom; as both caregivers and patients were able to correctly identify which treatment had been CORDStrom and which had been placebo in this cross-over study. With great interest from the patients to continue therapy, the Company intends to support a 12-month open label study at GOSH, including all patients enrolled in the MissionEB study, where patients will receive 3 cycles of CORDStrom therapy at time 0, 4 and 8 months.



The Company and the GOSH NHS Foundation Trust entered into an exclusive commercial license whereby the Company received exclusive commercial rights to the MissionEB clinical data in exchange for (i) payment of a small initial fee, (ii) a single development milestone fee that becomes due on receipt of the first to occur marketing authorization from the FDA, EMA, or MHRA, and (iii) a commitment to supply CORDStrom to MissionEB study patients that enroll in the open label study, subject to certain limitations.

The Company participated in a Type C meeting with the FDA, the outcome of which provided information related to CMC and other regulatory topics in anticipation of the Company's efforts to prepare and submit a BLA.

The FDA granted CORDStrom a rare pediatric disease designation (RPDD) for treatment of EB on December 13, 2024, ahead of the priority review voucher (PRV) sunset period, and as such, CORDStrom remains eligible to receive a PRV if approved by the FDA on or prior to September 30, 2026, which date may be extended by Congress. If granted, a PRV can be redeemed to receive priority review for a different product, or it may be transferred or sold.

Additionally, the FDA granted CORDStrom an orphan drug designation (ODD) on January 6<sup>th</sup>, 2025. Benefits of an ODD include certain tax credits and eligibility for select grants, waiver of FDA user fees, including the BLA application fees, access to frequent meetings with the FDA for efficient drug development, and eligibility for seven (7) years of market exclusivity post approval.

The Company intends to prepare for a pre-BLA meeting to discuss particulars of its planned BLA submission, with intent to submit a BLA in 2025 seeking approval of CORDStrom for the treatment of RDEB in pediatric patients. Concurrently, the company will also prepare to submit MAAs to the EU and UK in 2026.

"CORDStrom represents the culmination of years of dedication by members of our cell medicines R&D team to overcoming the challenges of creating a reproducible, cGMP grade MSC drug product at reasonable costs and scale to treat rare diseases like RDEB," said Dr. Mark Lowdell, CSO of INmune Bio and inventor of CORDStrom. "The encouraging results from the blinded randomized trial

in patients with intermediate and severe RDEB, combined with regulatory support and the NIHR grant, validate our approach and strengthen our resolve to deliver life-changing therapies for patients who need them most. We are heart warmed by the feedback from patients in the MissionEB study, the dedication of Dr. Anna Martinez and her group of investigators in completing this trial, all of which strengthens our resolve to seek approval for CORDStrom in pediatric RDEB and expand the indications for CORDStrom as a drug platform in the future.”

In addition to these developments involving CORDStrom, the Company reiterates plans to report top-line data on cognitive function in its MINDFuL study, a Phase II trial investigating Xpro™ for treatment of Alzheimer’s disease with inflammation, in June of this year, and further plans to announce additional data in its CaRe PC study, an open-label, phase I/IIa dose escalation and expansion study of INKmine in men with metastatic castration-resistant prostate cancer (mCRPC) as it becomes available throughout 2025.

The company will host a webinar at 8:30 AM ET today to discuss the results of the MissionEB study investigating CORDStrom for treatment of RDEB in pediatric patients.

Date: Monday, February 10, 2025

Time: 8:30 AM Eastern Time

Webcast: Click Here or <https://lifescievents.com/event/inmunebio-2/>

### **About CORDStrom**

CORDStrom is a patent-pending cell medicine comprising aseptic, allogeneic, pooled human umbilical cord -derived mesenchymal stromal cells (hucMSCs) in suspension for injection or infusion. The CORDStrom platform leverages, among other things, proprietary screening, pooling and expansion techniques to create off-the-shelf, allogeneic, pooled hucMSCs as medicines to treat complex inflammatory diseases. CORDStrom products are designed to provide high-quality, off-the-shelf, batch-to-batch consistent, scalable, cGMP manufactured, potent cellular medicines that can be produced at low cost and with repeatable specification independent of donor characteristics. The CORDStrom product platform shares many similarities, including reagents, equipment, and procedures, with the Company’s INKmine oncology product, enabling the Company to leverage economies of scale, experienced staff, and other resources to strategically manufacture both products in a rotational campaign with resource and environmental efficiencies.

Initially developed at the INKmine manufacturing facilities utilizing UK academic grant funding, CORDStrom is an MSC product platform that shows promise as a first systemic therapy for potentially treating RDEB and many other debilitating conditions. While the first generation CORDStrom product is agnostic to disease indication, the platform enables creation of indication-specific products, which can be tuned for optimization of anti-inflammatory, immunomodulatory, wound healing, and other characteristics.

### **About RDEB, DDEB, EB**

Epidermolysis Bullosa (EB) is a group of inherited skin disorders characterized by extreme skin fragility and blistering. Among its subtypes, Dystrophic Epidermolysis Bullosa (DEB) is notable for its division into Dominant Dystrophic EB (DDEB) and Recessive Dystrophic EB (RDEB), both caused by mutations in the COL7A1 gene which affects type VII collagen, crucial for skin adhesion. DDEB typically presents with milder symptoms, often limited to blistering on the hands, feet, elbows, and knees, with scarring, milia, and nail dystrophy being common. Conversely, RDEB is much more severe, with widespread blistering that can involve both external and internal mucous membranes, leading to significant complications like pseudosyndactyly, chronic wounds, severe scarring, and an increased risk of squamous cell carcinoma.

### **About INmune Bio Inc.**

**INmune Bio Inc.** is a publicly traded (NASDAQ: INMB), clinical-stage biotechnology company focused on developing treatments that target the innate immune system to fight disease. INmune Bio has three product platforms: the Dominant-Negative Tumor Necrosis Factor (DN-TNF) product platform utilizes dominant-negative technology to selectively neutralize soluble TNF, a key driver of innate immune dysfunction and a mechanistic driver of many diseases. DN-TNF product candidates are in clinical trials to determine if they can treat Mild Alzheimer’s disease, Mild Cognitive Impairment and treatment-resistant depression (XPro™). The Natural Killer Cell

Priming Platform includes INKmun<sup>®</sup> developed to prime a patient's NK cells to eliminate minimal residual disease in patients with cancer and is currently in trials in metastatic castration-resistance prostate cancer. The third program, CORDStrom, is a proprietary pooled, allogeneic, human umbilical cord-derived mesenchymal Stromal/Stem cell (hucMSCs) platform that recently completed a blinded randomized trial in recessive dystrophic epidermolysis bullosa. INmune Bio's product platforms utilize a precision medicine approach for diseases driven by chronic inflammation and cancer. To learn more, please visit [www.inmunebio.com](http://www.inmunebio.com).

### **Forward Looking Statements**

Clinical trials are in early stages and there is no assurance that any specific outcome will be achieved. Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations but are subject to a number of risks and uncertainties. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. CORDStrom, XPro1595 (XPro<sup>™</sup>), and INKmun<sup>™</sup> are still in clinical trials or preparing to start clinical trials and have not been approved by the US Food and Drug Administration (FDA) or any regulatory body and there cannot be any assurance that they will be approved by the FDA or any regulatory body or that any specific results will be achieved. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to produce more drug for clinical trials; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K, the Company's Quarterly Reports on Form 10-Q and the Company's Current Reports on Form 8-K. The Company assumes no obligation to update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this release.

**David Moss**

**Co-founder and Chief Financial Officer**

**(858) 964-3720**

**[info@inmunebio.com](mailto:info@inmunebio.com)**

**Daniel Carlson**

**Head of Investor Relations**

**(415) 509-4590**

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<u>Entity File Number</u>	001-38793
<u>Entity Registrant Name</u>	INMUNE BIO INC.
<u>Entity Central Index Key</u>	0001711754
<u>Entity Tax Identification Number</u>	47-5205835
<u>Entity Incorporation, State or Country Code</u>	NV
<u>Entity Address, Address Line One</u>	225 NE Mizner Blvd.
<u>Entity Address, Address Line Two</u>	Suite 640
<u>Entity Address, City or Town</u>	Boca Raton
<u>Entity Address, State or Province</u>	FL
<u>Entity Address, Postal Zip Code</u>	33432
<u>City Area Code</u>	858
<u>Local Phone Number</u>	964 3720
<u>Written Communications</u>	false
<u>Soliciting Material</u>	false
<u>Pre-commencement Tender Offer</u>	false
<u>Pre-commencement Issuer Tender Offer</u>	false
<u>Title of 12(b) Security</u>	Common Stock, par value \$0.001 per shares
<u>Trading Symbol</u>	INMB
<u>Security Exchange Name</u>	NASDAQ
<u>Entity Emerging Growth Company</u>	false









