

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): December 24, 2025

Emmaus Life Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35527

(Commission File Number)

87-0419387

(I.R.S. Employer
Identification No.)

21250 Hawthorne Boulevard, Suite 800, Torrance, CA

(Address of principal executive offices)

90503

(Zip Code)

Registrant's telephone number, including area code (310) 214-0065

(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:

- ☐ 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 240.13a-4(c))

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

Title of each class	Trading Symbol	Name of each exchange on which registered
None		

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 December 24, 2025, Emmaus Life Sciences, Inc. (“we,” “us,” “our,” “Emmaus” and the “company”) and NeoImmuneTech, Inc. (KOSDAQ: 950220.KQ), or NIT, entered into a License and Exclusive Distribution Agreement, or License Agreement, dated as of the same day pursuant to which we granted NIT an exclusive (including as to Emmaus) license to all our rights to market, sell and distribute Endari® (prescription grade L-glutamine oral powder) and any generic equivalents, or the Products, in sickle cell disease, or the Field, in the U.S. and its territories and possession and Canada, referred to as the Territory, in exchange for an upfront payment and a royalty on NIT’s Product sales. A portion of the upfront payment was paid in cash upon execution of the License Agreement, with the balance payable upon the “Effective Date” of the License Agreement.

In connection with the Effective Date, we and NIT will enter into an exclusive supply arrangement pursuant to which we will agree to supply exclusively to NIT, and NIT will agree, subject to certain exceptions, to purchase exclusively from us all NIT’s requirements for the Products in the Field in the Territory at a purchase price based upon our cost of production plus an agreed margin.

Pending the Effective Date, we facilitate the transfer and employment by NIT of selected members of our U.S. sales force.

The Effective Date is subject to NIT’s obtaining the necessary regulatory approvals and licensing to sell and distribute the Product and other specified conditions, and there is no assurance that the Effective Date will occur. The License Agreement may be terminated by either party if the Effective Date has not occurred by October 1, 2026 unless the failure to occur is due to our wrongful acts. Once the Effective Date occurs, the rights granted NIT under the License Agreement will become nonexclusive if NIT fails to generate specified annual minimum sales of Products. Following the Effective Date, the License Agreement may be terminated by either party in the event of a breach by the other party and other specified events.

Under the License Agreement, each party is entitled to make improvements to the Products and to own their respective improvements, subject to the grant of appropriate cross-rights to any such improvements. We retain all rights in the Products outside the Field and outside the Territory.

In connection with the Effective Date, the parties will enter into related quality, pharmacovigilance and support services agreement.

The foregoing descriptions of the material terms of the License Agreement and the exclusive supply arrangement are not complete and are qualified by reference to the full text of the same, copies of which will be filed as exhibits to our Annual Report on Form 10-K for the year ended December 31, 2025 and are incorporated herein by reference.

Item 8.01 Other Events.

On December 30, 2025, Emmaus issued a press release announcing the License Agreement and related matters. A copy of the press release is filed as Exhibit 99.1 to this Current Report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

See the accompanying Index to Exhibits, which information is incorporated herein by reference.

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.

Date: December 30, 2025

Emmaus Life Sciences, Inc.

By: /s/ WILLIS LEE

Willis Lee

Chairman and Chief Executive Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press release issued December 30, 2025
104	Cover Page Interactive Data File (embedded within Inline XBRL document)



**Emmaus Life Sciences Announces Strategic Transaction
Enters into North American License and Exclusive Distribution Agreement**

Torrance CA, December 30, 2025 - Emmaus Life Sciences, Inc. (OTCQB: EMMA), a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, today announced that it has entered into a License and Exclusive Distribution Agreement with NeoImmuneTech, Inc. (KOSDAQ: 950220.KQ), or NIT, pursuant to which Emmaus has granted NIT an exclusive license to all rights to market, sell and distribute Endari® (prescription grade L-glutamine oral powder) and any generic equivalents in sickle cell disease in the U.S. and its territories and possession, and Canada in exchange for a upfront payment and a royalty on NIT's product sales.

The effective date is subject to NIT's obtaining the necessary regulatory approvals and licensing to sell and distribute the products and other specified conditions.

"Emmaus has continuously reassessed its commercialization strategy to maximize global value of Endari®. While the U.S. market represents a mature and stable revenue base, we believe other regions such as the Middle East, Brazil, and Europe offer greater growth potential," commented Willis Lee, Chairman and Chief Executive Officer of Emmaus.

Tae Woo Kim, Acting Chief Executive Officer of NeoImmuneTech, said, "The completion of this definitive agreement is highly meaningful, as it establishes a foundation for direct commercialization of an FDA-approved therapy. The U.S. distribution, reimbursement, and marketing infrastructure built through Endari® will also create significant synergies for the future commercialization of our proprietary pipeline, including NT-I7."

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease. Endari® (L-glutamine oral powder), indicated to reduce the acute complications of sickle cell disease in adults and children 5 years and older, is approved for marketing in the United States, Israel, Kuwait, Qatar, the United Arab Emirates, Bahrain and Oman and is available on a named patient or early access basis in France, the Netherlands, and the Kingdom of Saudi Arabia, where Emmaus' application for marketing authorization is awaiting final action by the Saudi Food & Drug Authority. For more information, please visit www.emmausmedical.com.

About NeoImmuneTech, Inc.

NeoImmuneTech, Inc. (NIT) is a clinical-stage biopharmaceutical company specializing in T cell-based immunotherapy, with a mission to expand the potential of immuno-oncology and enhance immune responses to infectious diseases. Backed by a seasoned leadership team, NIT is advancing NT-I7 across multiple programs as a monotherapy and in combination with other immunotherapeutics. To learn more, please visit www.neoimmunetech.com.

About Endari® (prescription grade L-glutamine oral powder)

Endari®, Emmaus' prescription grade L-glutamine oral powder, was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older.

Indication

Endari® is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

Important Safety Information

The most common adverse reactions (incidence >10 percent) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremities, back pain, and chest pain.

Adverse reactions leading to treatment discontinuation included one case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

The safety and efficacy of Endari® in pediatric patients with sickle cell disease younger than five years of age has not been established.

For more information, please see full Prescribing Information of Endari® at: www.ENDARIr.com/PI.

About Sickle Cell Disease

There are approximately 100,000 people living with sickle cell disease (SCD) in the United States and millions more globally. The sickle gene is found in every ethnic group, not just among those of African descent; and in the United States an estimated 1-in-365 African Americans and 1-in-16,300 Hispanic Americans are born with SCD.¹ The genetic mutation responsible for SCD causes an individual's red blood cells to distort into a "C" or a sickle shape, reducing their ability to transport oxygen throughout the body. These sickled red blood cells break down rapidly, become very sticky, and develop a propensity to clump together, which causes them to become stuck and cause damage within blood vessels. The result is reduced blood flow to distal organs, which leads to physical symptoms of incapacitating pain, tissue and organ damage, and early death.²

¹Source: Data & Statistics on Sickle Cell Disease – National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, December 2020.²Source: Committee on Addressing Sickle Cell Disease – A Strategic Plan and Blueprint for Action -- National Academy of Sciences Press, 2020.

Forward-looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the possibility that the effective date of the License and Exclusive Distribution Agreement will not occur and doubt about Emmaus's ability to continue as a going concern and other factors disclosed in the company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on April 14, 2025 and Quarterly Report on Form 10-Q filed on November 14, 2025, and actual results may differ materially. Such forward-looking statements speak only as of the date they are made, and Emmaus assumes no duty to update them, except as may be required by law.

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