Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Abeona Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

83-0221517 (I.R.S. Employer Identification No.)

6555 Carnegie Ave, 4th Floor, Cleveland, OH 44103 (Address of Principal Executive Offices)

(Zip Code)

Second Amended and Restated Abeona Therapeutics Inc.

2023 Equity Incentive Plan (Full title of the plan)

Joseph Vazzano Chief Financial Officer Abeona Therapeutics Inc.

6555 Carnegie Ave, 4th Floor Cleveland, OH 44103

(646) 813-4701

(Name, address, and telephone number, including area code, of agent for service)

Copies of Correspondence to:

Sean M. Ewen, Esq. Jared N. Fertman, Esq. Willkie Farr & Gallagher LLP 787 Seventh Avenue New York, NY 10019-6099 (212) 728-8000

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Non-accelerated filer
 □
 Accelerated filer
 □

 ⊠
 Smaller reporting company
 ⊠

 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 7(a)(2)(B) of the Securities Act.

EXPLANATORY NOTE

This Registration Statement on Form S-8 (this "Registration Statement") is filed by Abeona Therapeutics Inc. (the "Registrant") to register an additional 5,200,000 shares of the Registrant's common stock, par value \$0.01 per share (the "Common Stock"), issuable under the Second Amended and Restated Abeona Therapeutics Inc. 2023 Equity Incentive Plan (the "Plan"), which was amended and restated on November 1, 2024 to increase the number of shares of Common Stock reserved for issuance thereunder, which amendment and restatement has been approved by the Registrant's shareholders.

Pursuant to the Registration Statements (the "Prior Registration Statements") on Form S-8 filed by the Registrant on May 19, 2023 (Registration No. 333-272103) and May 15, 2024 (Registration No. 333-279428), the Registrant previously registered an aggregate of 3,200,000 shares of Common Stock. The additional shares of Common Stock being registered by this Registration Statement are of the same class as those securities registered on the Prior Registration Statements and represent an increase in the total shares available for issuance under the Plan by 5,200,000. Pursuant to General Instruction E to Form S-8, the Registrant incorporates by reference into this Registration Statement the contents of the Prior Registration Statements, including all exhibits filed therewith or incorporated therein by reference, except as expressly modified herein.

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Item 3. Incorporation of Documents by Reference.

The following documents previously filed by the Abeona Therapeutics Inc. (the "Company" or "Registrant") with the Securities and Exchange Commission (the "Commission") are hereby incorporated by reference into this Registration Statement:

- (i) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (filed with the Commission on March 18, 2024);
- (ii) The Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024 (filed with the Commission on May 15, 2024);
- (iii) The Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024 (filed with the Commission on August 12, 2024);
- (iv) The Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 (filed with the Commission on November 14, 2024);
- (v) The Company's Current Reports on Form 8-K filed with the Commission on <u>April 22, 2024, April 24, 2024, May 3, 2024, May 3, 2024, July 9, 2024, August 14, 2024, October 29, 2024, November 12, 2024</u> and <u>December 20, 2024</u>; and
- (vi) The description of our common stock, par value \$0.01 per share contained in our Registration Statement on Form 8-A, dated and filed with the SEC on November 4, 2014, as updated by Exhibit 4.4 to our Form 10-K for the fiscal year ended December 31, 2019, and including any amendments or reports filed with the SEC for the purpose of updating such description.

To the extent that any information contained in any Current Report on Form 8-K, or any exhibit thereto, was furnished to, rather than filed with, the Commission, such information or exhibit is specifically not incorporated by reference.

All reports and other documents that the Company subsequently files with the Commission pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934, as amended, after the date of this Registration Statement and prior to the filing of a post-effective amendment that indicates that the Company has sold all of the securities offered under this Registration Statement or deregisters the distribution of all such securities then remaining unsold shall be deemed to be incorporated by reference in this Registration Statement and to be a part hereof from the date that the Company files such report or document.

Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any other subsequently filed document that also is, or is deemed to be, incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

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Item 8. Exhibits.

A list of exhibits filed herewith is contained in the Exhibit Index below, which is incorporated herein by reference.

EXHIBIT INDEX

| Exhibit | | | | | | Filed | | |
|---------|--|------------|-----------|------------|-------------------|----------|--|--|
| No. | Description | Form | File No. | Exhibit | Filing Date | Herewith | | |
| 4.1 | Restated Certificate of Incorporation of Abeona Therapeutics Inc. | 10-Q | 001-15771 | 3.1 | May 10, 2019 | | | |
| 4.2 | Certificate of Amendment to Restated Certificate of Incorporation of Abeona Therapeutics | 8-K | 001-15771 | 3.1 | June 30, 2022 | | | |
| | Inc. | | | | | | | |
| 4.3 | Second Amended and Restated Bylaws of Abeona Therapeutics Inc. | 8-K | 001-15771 | 3.1 | July 9, 2024 | | | |
| 5.1 | Opinion of Willkie Farr & Gallagher LLP | | | | | Х | | |
| 23.1 | Consent of Whitley Penn LLP | | | | | Х | | |
| 23.2 | Consent of Deloitte & Touche LLP | | | | | Х | | |
| 23.3 | Consent of Willkie Farr & Gallagher LLP (included in Exhibit 5.1 hereto) | | | | | Х | | |
| 24.1 | Powers of Attorney (included in the signature page of this Registration Statement) | | | | | Х | | |
| 99.1 | Second Amended and Restated Abeona Therapeutics Inc. 2023 Equity Incentive Plan | DEF 14A | 001-15771 | Appendix A | November 12, 2024 | | | |
| 107 | Filing Fee Table | | | | | Х | | |
| - 4 - | | | | | | | | |

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Morristown, in the state of New Jersey, on the 6th day of January, 2025.

ABEONA THERAPEUTICS INC.

By: /s/ Joseph Vazzano

Joseph Vazzano Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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POWER OF ATTORNEY

Each person whose signature appears below hereby appoints Vishwas Seshadri and Joseph Vazzano and each of them, severally, as his or her true and lawful attorney or attorneys-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and

all amendments to this Registration Statement (including all pre-effective and post-effective amendments and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, as amended), and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each act and thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons in the capacities and dates indicated.

| Signature | Title | Date |
|--|--|-----------------|
| /s/ Vishwas Seshadri Vishwas Seshadri | President, Chief Executive Officer and Director (Principal Executive Officer) | January 6, 2025 |
| /s/ Joseph Vazzano Joseph Vazzano | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | January 6, 2025 |
| /s/ Leila Alland Leila Alland | Director | January 6, 2025 |
| <u>/s/ Mark Alvino</u> Mark Alvino | Director | January 6, 2025 |
| /s/ Michael Amoroso Michael Amoroso | Director | January 6, 2025 |
| /s/ Faith Charles Faith Charles | Director | January 6, 2025 |
| /s/ Christine Silverstein Christine Silverstein | Director | January 6, 2025 |
| /s/ Donald Wuchterl Donald Wuchterl | Director | January 6, 2025 |
| /s/ Bernhardt Zeiher Bernhardt Zeiher | Director | January 6, 2025 |
| /s/ Eric Crombez Eric Crombez | Director | January 6, 2025 |
| | ſ | |

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WILLKIE FARR & GALLAGHER LLP

January 6, 2024

Abeona Therapeutics Inc. 6555 Carnegie Ave., 4th Floor Cleveland, OH 44103

Ladies and Gentlemen:

787 Seventh Avenue New York, NY 10019-6099 Tel: 212 728 8000 Fax: 212 728 8111

We have acted as counsel to Abeona Therapeutics Inc. (the "<u>Company</u>"), a corporation organized under the laws of the state of Delaware, with respect to the Company's Registration Statement on Form S-8 (the "<u>Registration Statement</u>") to be filed by the Company with the Securities and Exchange Commission (the '<u>Commission</u>") on or about the date hereof, in connection with the registration under the Securities Act of 1933, as amended (the "<u>Act</u>"), by the Company of an additional 5,200,000 shares of the Company's common stock, par value \$0.01 per share, of the Company (the "<u>Shares</u>") issuable in connection with the award of stock-based incentives (the "<u>Awards</u>") under the Second Amended and Restated Abeona Therapeutics Inc. 2023 Equity Incentive Plan (the "<u>Plan</u>").

We have examined, among other things, originals and/or copies (certified or otherwise identified to our satisfaction) of such documents, papers, statutes and authorities as we have deemed necessary to form a basis for the opinion hereinafter expressed. In our examination, we have assumed the genuineness of all signatures and the conformity to original documents of all copies submitted to us. As to various questions of fact material to our opinion, we have relied without independent check or verification upon statements, certificates and comparable documents of officers and representatives of the Company.

Based on the foregoing, we are of the opinion that the Shares issuable in connection with Awards under the Plan, when duly issued and delivered pursuant to the terms of the Awards and the Plan, will be validly issued, fully paid and non-assessable.

This opinion is limited to the General Corporation Law of the State of Delaware, and we express no opinion with respect to the laws of any other jurisdiction or any other laws of the State of Delaware. This opinion speaks only as of the date hereof and is limited to present statutes, regulations and administrative and judicial interpretations. We undertake no responsibility to update or supplement this letter after the date hereof.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act.

Very truly yours,

/s/ Willkie Farr & Gallagher LLP

Brussels Chicago Frankfurt Houston London Los Angeles Milan Munich New York Palo Alto Paris Rome San Francisco Washington

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-8 of Abeona Therapeutics Inc. of our report dated March 29, 2023, relating to the consolidated financial statements as of and for the year ended December 31, 2022, appearing in the Annual Report on Form 10-K of Abeona Therapeutics Inc. for the year ended December 31, 2023.

/s/ Whitley Penn LLP

Plano, Texas January 6, 2025

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-8 of our report dated March 15, 2024 relating to the financial statements of Abeona Therapeutics Inc., appearing in the Annual Report on Form 10-K of Abeona Therapeutics Inc. for the year ended December 31, 2023.

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey January 6, 2025

Calculation of Filing Fee Table

Form S-8

(Form Type)

ABEONA THERAPEUTICS INC. (Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities.

| Security Type | Security Class Title | Fee Calculation Rule | Amount Registered ⁽¹⁾ | 0 | Proposed Maximum ffering Price Per Share ⁽²⁾ | | Maximum Aggregate ffering Price (2) | Fee Rate | | Amount of Registration Fee | |
|---------------|---------------------------------------|-------------------------|-------------------------------------|----|--|----|--|------------|----------|-------------------------------|--|
| | Common stock, par value \$0.01 per | Rule 457(c) and | 5 200 000 (3) | • | 5.50 | ¢ | 20.016.000 | 0.00015210 | <i>•</i> | 1 110 05 | |
| Equity | share | 457(h) | 5,200,000 ⁽³⁾ | \$ | 5.58 | \$ | 29,016,000 | 0.00015310 | \$ | 4,442.35 | |
| | | Тс | tal Offering Amounts | | | \$ | 29,016,000 | | \$ | 4,442.35 | |
| | | | Total Fee Offsets | | | | | | \$ | 0.00 | |
| | | | Net Fees Due | | | | | | \$ | 4,442.35 | |

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the "Securities Act"), the Registration Statement on Form S-8 to which this exhibit relates shall be deemed to cover an indeterminate amount of additional shares of the registrant's common stock, par value \$0.01 per share (the "Common Stock"), that may be offered and issued pursuant to the registrant's Second Amended and Restated Abeona Therapeutics Inc. 2023 Equity Incentive Plan (the "Plan") as a result of any share split, share dividend, recapitalization or similar transactions affecting the Common Stock.

(2) Calculated pursuant to Rules 457(c) and 457(h) under the Securities Act solely for the purpose of calculating the registration fee. The registration fee is calculated based on a price of \$5.58 per share, which is the average of the high and low prices of the Common Stock as reported on the Nasdaq Capital Market on December 30, 2024.

(3) Represents the additional 5,200,000 shares of Common Stock reserved and available for issuance under the Plan on December 20, 2024.

Table 2: Fee Offset Claims and Sources

Not applicable.