

PROSPECTUS SUPPLEMENT
(To Prospectus dated April 25, 2025)



Clene Inc.

1,219,513 Shares of Common Stock

We are offering 1,219,513 shares of our common stock, par value \$0.0001 per share (“common stock”) at an offering price of \$3.28 per share directly to certain of our existing stockholders, including certain of our directors and officers, (the “Purchasers”) in this offering pursuant to this prospectus supplement, the accompanying base prospectus and a securities purchase agreement, dated September 15, 2026 (the “Securities Purchase Agreement”). This offering is being made without a placement agent, underwriter, broker or dealer and we are not paying underwriting discounts or commissions, so we expect the proceeds to us, before expenses, will be approximately \$4.0 million. We estimate the total offering expenses will be insignificant.

Certain of our directors and officers have agreed to purchase shares of our common stock in this offering with an aggregate purchase price of approximately \$2.1 million at the offering price. The offering price to directors and officers is equal to or greater than the consolidated closing bid price immediately preceding the time we entered into the Securities Purchase Agreement with such directors and officers.

Our common stock is listed on The Nasdaq Capital Market (“Nasdaq”) under the symbol “CLNN.” On September 14, 2026, the last reported sale price of our common stock on Nasdaq was \$3.28.

Investing in our securities involves a high degree of risk. See “Risk Factors” section beginning on page S-9 and in the documents incorporated by reference herein.

We are a “smaller reporting company,” as that term is defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements and may elect to do so in future filings.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock is expected to be made on or about September 16, 2026.

The date of this prospectus supplement is September 15, 2026.

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Prospectus

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is part of a Registration Statement on Form S-3 (the “Registration Statement”) that we filed with the U.S. Securities and Exchange Commission (“SEC”) using the “shelf” registration process. By using a shelf registration statement, we may offer and sell securities having an aggregate offering price of up to \$160,000,000 from time to time under the Registration Statement at prices and on terms to be determined by market conditions at the time of offering.

This prospectus supplement provides you with a description of the offering. You should read this prospectus supplement together with the additional information to which we refer you in the section of this prospectus supplement titled “*Where You Can Find More Information*,” and together with the information incorporated by reference as described in the section of this prospectus supplement titled “*Information Incorporated By Reference*.”

We provide information to you about this offering in two separate documents that are bound together: (i) this prospectus supplement, which describes the specific details regarding this offering; and (ii) the accompanying base prospectus, which provides general information, some of which may not apply to this offering. Generally, when we refer to this “prospectus,” we are referring to both documents combined. If information in this prospectus supplement is inconsistent with the accompanying base prospectus, you should rely on this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in any document incorporated by reference in this prospectus supplement, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in this prospectus supplement—the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information incorporated by reference or set forth in this prospectus supplement. We have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus supplement. We do not take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement is accurate only as of the date on the front cover of this prospectus supplement. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus supplement in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus supplement outside of the United States.

We urge you to read carefully this prospectus supplement, together with information incorporated by reference herein, before deciding whether to invest in the securities being offered.

This prospectus supplement and the accompanying base prospectus contain summaries of certain provisions contained in some of the documents described herein or therein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein or therein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus supplement is a part, and you may obtain copies of those documents as described under “Where You Can Find More Information.”

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus supplement are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus supplement may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the other documents we have filed with the SEC that are incorporated by reference herein contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 27A of the Securities Act of 1933, as amended (the “Securities Act”). Certain statements in this prospectus supplement may constitute “forward-looking statements” for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions, or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this prospectus supplement may include, for example, statements about:

- our future financial performance, including our ability to continue as a going concern;
- our plans and strategies to raise additional funding;
- the clinical results of our drug candidates;
- the likelihood of commercial success for our drug candidates;
- our plans and strategies to obtain and maintain regulatory approvals of our drug candidates;
- the size and growth potential of the markets for our drug candidates, and our ability to serve those markets, either alone or in combination with others;
- changes in the market for our drug candidates;
- expansion plans and opportunities; and
- other factors detailed under “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q.

These forward-looking statements represent our views as of the date of this prospectus supplement and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date.

As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include:

- our substantial dependence on the successful commercialization of our drug candidates, if approved, in the future;
- our significant net losses and net operating cash outflows;
- our ability to demonstrate the efficacy and safety of our drug candidates;
- the clinical results for our drug candidates, which may not support further development or marketing approval;
- actions of regulatory agencies, which may affect the initiation, timing, and progress of clinical trials and marketing approval;
- our ability to achieve commercial success for our drug candidates, if approved;
- our ability to obtain and maintain protection of intellectual property for our technology and drug candidates;
- our reliance on third parties to conduct research, drug development, and other services;
- our limited operating history and our ability to obtain additional funding for operations and to complete the licensing or development and commercialization of our drug candidates;

- the impact of any future epidemics, pandemics or conflicts;
- changes in applicable laws or regulations;
- the effects of inflation;
- the effects of staffing and materials shortages;
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties set forth in “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus supplement, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements.

MARKET AND INDUSTRY DATA

We obtained the industry and market data used throughout this prospectus supplement from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, publicly available information and research, surveys, and studies by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry and market data included in this prospectus supplement is reliable and based on reasonable assumptions, such data involve material risks and other uncertainties and are subject to change based on various factors, including those discussed in “*Risk Factors*.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information from this prospectus supplement and does not contain all of the information that is important to you in making an investment decision. This summary is qualified in its entirety by the more detailed information included elsewhere in this prospectus supplement. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus supplement, the accompanying base prospectus, and the information incorporated herein and therein by reference. Unless the context otherwise requires, references to “we,” “us,” “our,” “the Company,” “Clene,” and similar designations are intended to mean the business and operations of Clene Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage pharmaceutical company pioneering the discovery, development, and commercialization of novel clean-surfaced nanotechnology (“CSN®”) therapeutics. CSN® therapeutics are comprised of atoms of transition elements that, when assembled in nanocrystal form, possess unusually high, unique catalytic activities not present in those same elements in bulk form. These catalytic activities drive, support, and maintain beneficial metabolic and energetic cellular reactions within diseased, stressed, and damaged cells.

Our patent-protected, proprietary position affords us the potential to develop a broad and deep pipeline of novel CSN therapeutics to address a range of diseases with high impact on human health. We innovated an electro-crystal-chemistry drug development platform that draws from advances in nanotechnology, plasma and quantum physics, material science, and biochemistry. Our platform process results in nanocrystals with faceted structures and surfaces that are free of the chemical surface modifications that accompany other production methods. Many traditional methods of nanoparticle synthesis involve the unavoidable deposition of potentially toxic organic residues and stabilizing surfactants on the particle surfaces. Synthesizing stable nanocrystals that are both nontoxic and highly catalytic has overcome this significant hurdle in harnessing transition metal catalytic activity for therapeutic use. Our clean-surfaced nanocrystals exhibit catalytic activities many-fold higher than other commercially available nanoparticles, produced using various techniques, that we have comparatively evaluated.

Our development and clinical efforts are dedicated to revolutionizing the treatment of neurodegenerative diseases to restore and protect neuronal health and function. Our nanotherapeutics target cellular energy impairments that are common to many diseases and we are currently focused on addressing the high unmet medical needs in central nervous system disorders including amyotrophic lateral sclerosis (“ALS”), multiple sclerosis (“MS”), and Parkinson’s disease (“PD”). We currently have no drugs approved for commercial sale and have not generated any revenue from drug sales. We have never been profitable and have incurred operating losses in each year since inception. We generate revenue from sales of dietary supplements through our wholly owned subsidiary, dOrbital, Inc., or through an exclusive license with 4Life Research LLC (“4Life”), an international supplier of health supplements, stockholder, and related party. We anticipate these revenues to be small compared to our operating expenses and to the revenue we expect to generate from potential future sales of our drug candidates, for which we are currently conducting clinical trials.

Recent Developments of Our Clinical Programs

Amyotrophic Lateral Sclerosis

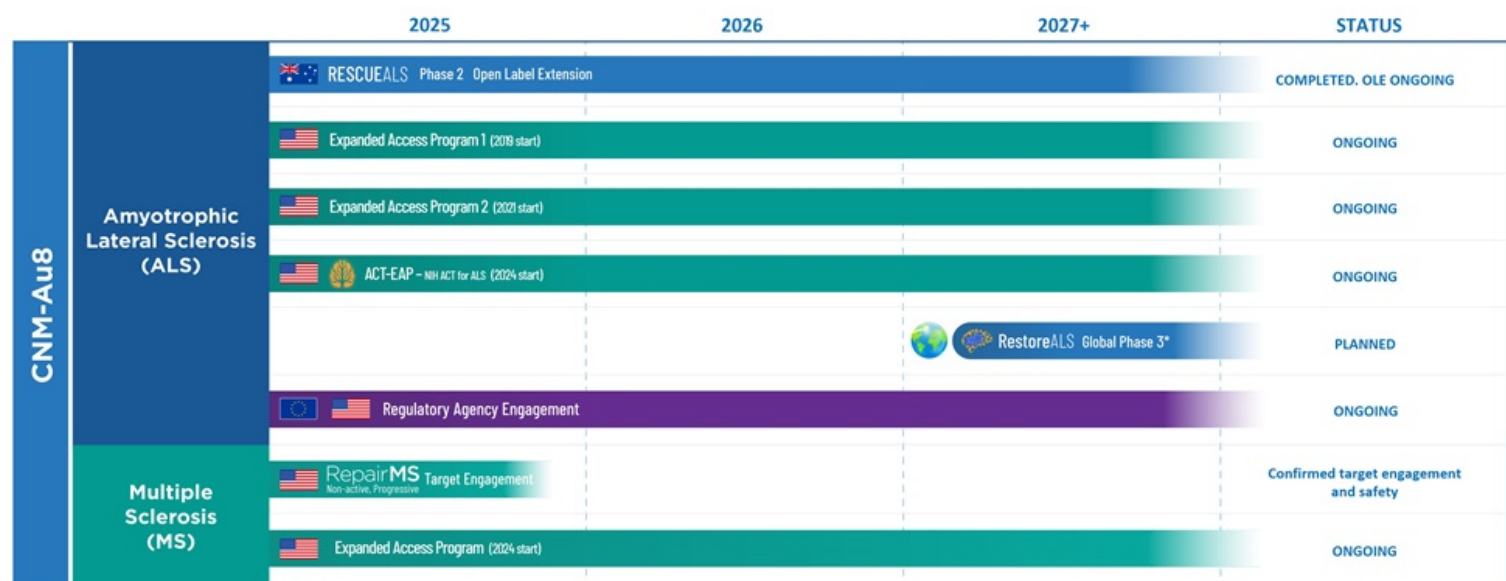
In August 2026, we announced the results from new biomarker analyses examining clinical outcomes among CNM-Au8®-treated patients in our two completed Phase 2 ALS trials. Patients whose neurofilament light chain (“NfL”) biomarker levels declined or stabilized lived significantly longer than concurrently randomized controls and had significantly better outcomes on combined measures of survival and function, including daily function (ALSFRS-R) and breathing capacity (Slow Vital Capacity), than concurrently randomized controls. These post hoc exploratory findings will be included in our planned new drug application (“NDA”) seeking accelerated approval and are intended to address the questions raised by the U.S. Food and Drug Administration (“FDA”) during a March 2026 Type C meeting. At that meeting, the FDA acknowledged that NfL, a recognized blood marker of nerve-cell injury, has established prognostic value in ALS and could potentially serve as a reasonably likely surrogate endpoint to support accelerated approval.

We intend to submit our NDA in early fourth quarter of 2026, which will remain a matter of FDA review. The planned NDA submission will be supported by NfL biomarker and clinical data from the Phase 2 HEALEY ALS Platform Trial and its open-label extension, as well as the Phase 2 RESCUE-ALS Trial, and the National Institutes of Health-sponsored expanded access protocol for CNM-Au8. We plan to initiate a Phase 3 RESTORE-ALS trial during the second quarter of 2027, which will serve as the post-approval confirmatory study.

Multiple Sclerosis

We met with the FDA in a Type B end of Phase 2 meeting during the third quarter of 2025 to review results from the Phase 2 VISIONARY-MS trial and discuss a planned Phase 3 study focusing on cognition improvement as an adjunct to standard-of-care MS therapies, addressing a critical unmet medical need for people struggling with MS. The FDA aligned with the Company acknowledging the limitations of the Expanded Disability Status Scale, a global measure of MS disease severity, and expressed openness to considering other potential primary endpoints, including cognition, to evaluate broader treatment effects. We plan to work closely with regulatory health authorities from the FDA, European Medicines Agency and other international regulatory bodies, MS experts, and patient representatives to determine the proper path to advance CNM-Au8 into Phase 3 and potential future approval. We also believe that once CNM-Au8 receives regulatory approval in another indication, licensing opportunities for the MS indication will improve.

The chart below reflects the growing body of evidence for CSN therapeutics from our completed and ongoing clinical programs.



*Contingent on funding

Going Concern

We incurred a loss from operations of \$5.3 million and \$5.9 million for the three months ended June 30, 2026 and 2025, respectively; and \$7.4 million and \$9.9 million for the six months ended June 30, 2026 and 2025, respectively. Our accumulated deficit was \$329.8 million and \$308.3 million as of June 30, 2026 and December 31, 2025, respectively. Our cash and cash equivalents totaled \$9.7 million and \$5.2 million as of June 30, 2026 and December 31, 2025, respectively, and net cash used in operating activities was \$7.1 million and \$9.8 million for the six months ended June 30, 2026 and 2025, respectively.

We have incurred significant losses and negative cash flows from operations since our inception. We have not generated significant revenues since our inception, and we do not anticipate generating significant revenues unless we successfully complete development and obtain regulatory approval for commercialization of a drug candidate. We expect to incur additional losses in the future, particularly as we advance the development of our clinical-stage drug candidates, continue research and development of our preclinical drug candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our senior secured convertible promissory notes issued in December 2024 (the “2024 SSCP Notes”), we are required to maintain unrestricted cash and cash equivalents of at least \$2.0 million to avoid acceleration of the full balance of the 2024 SSCP Notes. These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

To mitigate our funding needs, we plan to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as utilizing our existing at-the-market facility and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the three and six months ended June 30, 2026, we raised \$7.0 million and \$13.0 million, respectively, of gross proceeds from registered direct offerings of equity securities. While we have implemented cost-saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts, reducing employee compensation, and eliminating certain staff positions, we have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date the condensed consolidated financial statements for the quarter ended June 30, 2026, were issued.

Our financial statements incorporated herein by reference have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result, our financial statements incorporated herein by reference do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

Smaller Reporting Company Status

We are a “smaller reporting company” because the market value of our stock held by non-affiliates was less than \$250 million as of June 30, 2026. We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million as of June 30 in the most recently completed fiscal year. As a smaller reporting company, we are eligible for and may take advantage of certain exemptions from various reporting requirements applicable to other public companies for as long as we continue to be a smaller reporting company, including (i) the choice of presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, (ii) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Corporate History and Information

Clene Nanomedicine, Inc. (“Clene Nanomedicine”) became a public company on December 30, 2020 (the “Closing Date”) when it completed a reverse recapitalization (the “Reverse Recapitalization”) with Tottenham Acquisition I Limited (“Tottenham”), and with Tottenham’s wholly-owned subsidiary and our predecessor, Chelsea Worldwide Inc., and Creative Worldwide Inc., a wholly-owned subsidiary of Chelsea Worldwide Inc. On the Closing Date, Chelsea Worldwide Inc. changed its name to Clene Inc. and listed its shares of common stock, par value \$0.0001 per share (“common stock”), on Nasdaq under the symbol “CLNN.”

We effected a 1-for-20 reverse stock split of our common stock beginning with the opening of trading on July 11, 2024 (the “Reverse Stock Split”). As a result, every 20 shares of our common stock issued and outstanding were automatically combined and converted into 1 validly issued, fully paid and non-assessable share. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of our common stock were adjusted as a result of the Reverse Stock Split, in accordance with the terms of each such security. In addition, the number of shares reserved for issuance pursuant to our Amended 2020 Stock Plan was also appropriately adjusted. All historical share and per share data for the periods presented in this prospectus supplement, including for periods ending prior to July 11, 2024, has been adjusted to reflect the 1-for-20 Reverse Stock Split.

The mailing address for our principal executive office is 6550 South Millrock Drive, Suite G50, Salt Lake City, Utah 84121, and our telephone number is (801) 676-9695. Our website address is <https://clene.com>. The information contained in or accessible from our website is not incorporated into this prospectus supplement, and you should not consider it part of this prospectus supplement. We have included our website address in this prospectus supplement solely as an inactive textual reference.

THE OFFERING

Shares of common stock being offered by us	1,219,513 shares of our common stock.
Shares of common stock to be outstanding immediately after this offering	14,213,981 shares of our common stock.
Use of proceeds	We expect to use the net proceeds from the offering, together with our existing cash, for expenses primarily related to general corporate purposes, including to fund the effort supporting the continued regulatory dialogue and preparation of regulatory filings and a new drug application for our lead drug candidate, CNM-Au8, including expanded access protocols, potential future commercialization efforts and manufacturing expansion. See “ <i>Use of Proceeds</i> ” for additional information.
Insider participation	Certain of our directors have agreed to purchase shares of our common stock in this offering with an aggregate purchase price of approximately \$2.1 million at the offering price.
Risk factors	Any investment in the securities offered hereby is speculative and involves a high degree of risk. You should read carefully the information set forth in “ <i>Risk Factors</i> ” in this prospectus supplement and the accompanying base prospectus, together with other information included elsewhere in this prospectus supplement, or incorporated by reference into this prospectus supplement, for a discussion of factors that you should consider before deciding to invest in our securities.
Nasdaq Capital Market symbol	“CLNN”

The number of shares of our common stock outstanding immediately after this offering is based on 12,994,468 shares of common stock outstanding as of September 14, 2026, and excludes the following:

- 3,474,923 shares of common stock issuable upon exercise of stock options outstanding as of September 14, 2026 with a weighted-average exercise price of \$17.73 per share;
- 837,798 shares of common stock reserved for future grant under our 2020 Stock Plan as of September 14, 2026;
- 7,910,247 shares of common stock issuable upon exercise of warrants outstanding as of September 14, 2026 with a weighted-average exercise price of \$13.33 per share; and
- up to 1,637,710 shares of common stock issuable upon conversion of our convertible notes payable outstanding as of September 14, 2026.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of the outstanding options or warrants or conversion of convertible notes payable referred to above.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should carefully consider the risks and uncertainties described below and under “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, which are incorporated herein by reference, together with the information contained in this prospectus supplement, the accompanying base prospectus, and any other information that has been or will be incorporated herein or therein by reference. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations, and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. The risk factors are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This prospectus supplement also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially and adversely from those anticipated in the forward-looking statements as a result of a number of factors. See “Cautionary Note Regarding Forward-Looking Statements.”

Risks Related to Our Securities and this Offering

The market for our common stock may not provide investors with adequate liquidity.

Our common stock is currently listed on Nasdaq. However, the trading market for our common stock may not be maintained and may not provide investors with adequate liquidity. The liquidity of the market for our common stock depends on a number of factors, including prevailing interest rates, our financial condition and operating results, the number of holders of our common stock, the market for similar securities and the interest of securities dealers in making a market in our common stock. We cannot predict the extent to which investor interest in our Company will maintain the trading market in our common stock, or how liquid that market will be. If an active market is not maintained, investors may have difficulty selling shares of our common stock.

Future sales or issuances of our common stock in the public markets, or the perception of such sales, could depress the trading price of our common stock.

The sale of a substantial number of shares of our common stock or other equity-related securities in the public markets, or the perception that such sales could occur, could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We may sell large quantities of our common stock pursuant to this prospectus supplement and/or in one or more separate offerings. We cannot predict the effect that future sales of common stock or other equity-related securities would have on the market price of our common stock.

Our management will have broad discretion over the use of the net proceeds we receive in this offering and may not apply the proceeds in ways that increase the value of your investment, which could cause the market price of our common stock to decline.

Our management will have broad discretion to use the net proceeds payable to us from this offering and you will be relying on the judgment of our management regarding the application of these net proceeds. Our management might not apply the net proceeds from this offering in ways that increase the value of your investment. Until we use the net proceeds payable to us from this offering, we plan to invest them, and these investments may not yield a favorable rate of return. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause the market price of our common stock to decline.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing shares of our common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share of our common stock. As a result, investors purchasing shares of our common stock in this offering will experience immediate dilution of \$4.77 per share, representing the difference between the public offering price of \$3.28 per share and our pro forma as adjusted net tangible book value per share as of June 30, 2026. To the extent outstanding options or warrants to purchase our common stock are exercised, you may experience further dilution. For more information on the dilution you may experience as a result of investing in this offering, see the section of this prospectus supplement entitled “*Dilution*.”

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be lower than the price per share paid by investors in this offering.

We may require additional financing to sustain our operations, without which we may not be able to continue operations, and the terms of subsequent financings may adversely impact our stockholders.

We may still need additional capital to finance our future plans and working capital needs, and we may have to raise funds through the issuance of equity or debt securities. Depending on the type and the terms of any financing we pursue, stockholders’ rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, convertible debt, or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, the holders of our outstanding debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition, and prospects.

USE OF PROCEEDS

We estimate the net proceeds from this offering will be approximately \$4.0 million from the sale of our common stock, after deducting offering expenses payable by us.

We expect to use the net proceeds from the offering, together with our existing cash, for expenses primarily related to general corporate purposes, including to fund the effort supporting the continued regulatory dialogue and preparation of regulatory filings and a new drug application for our lead drug candidate, CNM-Au8, including expanded access protocols, potential future commercialization efforts and manufacturing expansion.

The expected use of net proceeds represents our intentions, based upon our present plans and business conditions. We cannot specify with certainty all of the particular uses for the net proceeds. Due to uncertainties inherent in the drug development process, it is difficult to estimate the exact amounts of the net proceeds that will be used for any particular purpose. We may use our existing cash and the future payments, if any, generated from any future collaboration agreements to fund our operations, either of which may alter the amount of net proceeds used for a particular purpose. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of clinical trials, and the timing of regulatory submissions. Accordingly, we will have broad discretion in using these net proceeds.

We intend to invest the net proceeds we receive that are not used as described above in a variety of capital preservation investments, including investment-grade, interest-bearing instruments and certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have not declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

DESCRIPTION OF SECURITIES

Common Stock

The material terms of our common stock are described under the heading “*Description of Capital Stock*” in the accompanying base prospectus and in the “*Description of Securities of the Registrant*” included as Exhibit 4.1 to our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 17, 2026.

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. Our common stock is listed on the Nasdaq Capital Market under the symbol “CLNN.”

DILUTION

If you invest in our securities in this offering, you will experience immediate and substantial dilution to the extent of the difference between the public offering price per share of our common stock and the adjusted net tangible book value per share of our common stock immediately upon the consummation of this offering. Net tangible book value per share represents the book value of our tangible assets less the book value of our total liabilities divided by the number of shares of common stock then issued and outstanding.

Our historical net tangible book value (deficit) as of June 30, 2026 was \$(24.8) million, or (\$1.94) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by 12,778,307 shares of our common stock outstanding as of June 30, 2026.

After giving effect to 1,219,513 shares of our common stock issued and sold in this offering at an offering price of \$3.28 per share, and after deducting estimated offering expenses payable by us, our as adjusted net tangible book value (deficit) as of June 30, 2026 would have been \$(20.8) million, or (\$1.49) per share. This represents an immediate increase in as adjusted net tangible book value (deficit) per share of \$0.45 to existing stockholders and an immediate dilution of \$4.77 in as adjusted net tangible book value (deficit) per share to investors purchasing our securities in this offering. Dilution per share to investors purchasing our securities in this offering is determined by subtracting as adjusted net tangible book value (deficit) per share after this offering from the public offering price per share paid by investors.

The following table illustrates this dilution on a per share basis:

Public offering price per share		\$	3.28
Historical net tangible book value (deficit) per share	\$	(1.94)	
Increase in historical net tangible book value per share attributable to this offering	\$	0.45	
As adjusted net tangible book value (deficit) per share after this offering	\$	(1.49)	
Dilution per share to investors participating in this offering		\$	<u>4.77</u>

The foregoing tables and calculations (other than the historical net tangible book value (deficit) calculations) are based on 12,778,307 shares of our common stock outstanding as of June 30, 2026, and excludes the following:

- 3,458,957 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2026 with a weighted-average exercise price of \$17.81 per share;
- 853,764 shares of common stock reserved for future grant under our 2020 Stock Plan as of June 30, 2026;
- 7,910,247 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2026 with a weighted-average exercise price of \$13.33 per share; and
- up to 1,597,714 shares of common stock issuable upon conversion of our convertible notes payable outstanding as of June 30, 2026.

To the extent that stock options, warrants, or convertible notes payable outstanding as of June 30, 2026 are exercised or converted to shares of common stock at prices below the prices paid by investors participating in this offering, investors in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

PLAN OF DISTRIBUTION

We have arranged for the sale of 1,219,513 shares of our common stock at an offering price of \$3.28 per share directly to the Purchasers pursuant to this prospectus supplement, the accompanying base prospectus and a Securities Purchase Agreement by and among us and the Purchasers. This offering is being made without a placement agent, underwriter, broker or dealer. On the closing date, we will issue the shares of common stock to the Purchasers and we will receive proceeds, before expenses, of approximately \$4.0 million. We estimate the total offering expenses payable by us in connection with this offering will be insignificant. The closing of this offering is subject to customary closing conditions.

Certain of our directors and officers have agreed to purchase shares of our common stock in this offering with an aggregate purchase price of approximately \$2.1 million at the offering price.

Pursuant to the Securities Purchase Agreement, we agreed to indemnify the Purchasers against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the Securities Purchase Agreement. The Securities Purchase Agreement contains customary representations, warranties and agreements by us and customary conditions to closing.

For the complete terms of the Securities Purchase Agreement, you should refer to the form of the Securities Purchase Agreement, which will be filed as an exhibit to a Current Report on Form 8-K filed with the SEC in connection with this offering and which is incorporated by reference into the registration statement of which this prospectus supplement forms a part. We expect to deliver the securities being offered pursuant to this prospectus supplement on or about September 16, 2026, subject to satisfaction of customary closing conditions.

LEGAL MATTERS

The validity of the securities offered pursuant to this prospectus supplement will be passed upon by Dorsey & Whitney LLP.

EXPERTS

The financial statements of Clene Inc. as of and for the years ended December 31, 2025 and 2024, incorporated by reference in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are incorporated by reference in reliance upon the report of such firm given their authority as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3, including exhibits, under the Securities Act, with respect to the securities offered pursuant to this prospectus supplement. This prospectus supplement is part of the registration statement, but does not contain all of the information included in the registration statement or the exhibits. For further information with respect to us and the securities offered by this prospectus supplement, we refer you to the registration statement and its exhibits. Statements contained in this prospectus supplement as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

In addition, we file annual, quarterly, and current reports, proxy statements, and other information with the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including our SEC filings, located at <https://www.sec.gov>. We also maintain a website at <https://clene.com>. The information contained in or accessible from our website is not incorporated into this prospectus supplement, and you should not consider it part of this prospectus supplement. We have included our website address in this prospectus supplement solely as an inactive textual reference. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus supplement, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus supplement or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or a subsequently filed document incorporated by reference modifies or replaces that statement.

This prospectus supplement incorporates by reference the documents set forth below that have previously been filed with the SEC:

- our Annual Report on [Form 10-K](#) for the year ended December 31, 2025, filed with the SEC on March 17, 2026;
- our Quarterly Reports on Form 10-Q for the quarter ended [March 31, 2026](#), filed with the SEC on May 14, 2026, and the quarter ended [June 30, 2026](#), filed with the SEC on August 14, 2026;
- our Current Reports on Form 8-K filed with the SEC on [January 12, 2026](#), [January 13, 2026](#), [February 24, 2026](#), [March 17, 2026](#), [May 4, 2026](#) (with respect to Item 8.01 only), [May 5, 2026](#), [May 14, 2026](#) (with respect to Item 1.01 only), [May 22, 2026](#), and [August 10, 2026](#) (with respect to Item 8.01 only);
- the information specifically incorporated by reference into our Annual Report on [Form 10-K](#) for the year ended December 31, 2025 from our Definitive Proxy Statement on [Schedule 14A](#), filed with the SEC on April 10, 2026; and
- the description of our common stock contained in [Exhibit 4.1](#) to our Form 10-K filed with the SEC on March 17, 2026.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14, or 15(d) of the Exchange Act prior to the termination of this offering, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus supplement and deemed to be part of this prospectus supplement from the date of the filing of such reports and other documents.

We will provide to each person, including any beneficial owner, to whom a prospectus supplement is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus supplement but not delivered with the prospectus supplement. You may request a copy of any documents incorporated by reference in this prospectus supplement and the accompanying base prospectus, at no cost, by writing or telephoning us at:

Clene Inc.
Attention: Investor Relations
6550 South Millrock Drive, Suite G50
Salt Lake City, Utah 84121
Telephone: (801) 676-9695

Exhibits to the filings will not be sent, however, unless those exhibits have been specifically incorporated by reference in this prospectus supplement.

\$160,000,000



Clene Inc.

**Common Stock
Preferred Stock
Debt Securities
Warrants
Units**

From time to time, we may offer and sell up to \$160,000,000 aggregate dollar amount of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, and/or units consisting of some or all of these securities, in any combination, together or separately, in one or more offerings, in amounts, at prices and on the terms that will be determined at the time of the offering and which will be set forth in a prospectus supplement. The prospectus supplement may also add, update or change information contained in this prospectus.

The securities may be sold directly to investors, through agents designated from time to time or to or through underwriters or dealers, on a continuous or delayed basis. If any agents, underwriters or dealers are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such agents, underwriters or dealers and any applicable fees, commissions, discounts and over-allotment options will be set forth in a prospectus supplement.

You should read this prospectus and any prospectus supplement or amendment carefully before you invest in our securities. This prospectus may not be used to consummate sales of these securities unless it is accompanied by a prospectus supplement.

Our common stock and public warrants are listed on the Nasdaq Capital Market ("Nasdaq") under the symbols "CLNN" and "CLNNW," respectively. On April 24, 2025, the last reported sale price of our common stock and public warrants on Nasdaq was \$3.17 and \$0.0345, respectively.

As of April 24, 2025, the aggregate market value of our common stock held by our non-affiliates, as calculated pursuant to the rules of the SEC, was approximately \$34.7 million, based upon 7,568,652 shares of our outstanding common stock held by non-affiliates at the per share price of \$4.58, the closing sale price of our common stock on Nasdaq on March 7, 2025 which is within 60 days of the date of this prospectus. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a public offering with a value exceeding more than one-third of our "public float" (i.e., the market value of our common stock held by our non-affiliates) in any 12-month period so long as our public float remains below \$75.0 million. We have sold \$9.6 million of securities in reliance on General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

Investing in our securities involves a high degree of risk. See "Risk Factors" section on page 9 of this prospectus and other risk factors contained in any applicable prospectus supplement and in the documents incorporated by reference herein and therein.

We are a "smaller reporting company," as that term is defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements and may elect to do so in future filings.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 25, 2025.

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ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement on Form S-3 (the “Registration Statement”) that we filed with the U.S. Securities and Exchange Commission (“SEC”) using the “shelf” registration process. Under this shelf registration process, we may offer and sell shares of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, and/or units, either individually or in combination with other securities, in one or more offerings, up to a total dollar amount of \$160,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. The prospectus supplement may also add information to, or update or change information contained in, this prospectus. You should read both this prospectus and any applicable prospectus supplement or post-effective amendment to the Registration Statement, together with the additional information to which we refer you in the section of this prospectus entitled “*Where You Can Find More Information*,” and together with the information incorporated by reference as described in the section of this prospectus entitled “*Information Incorporated By Reference*.”

You should rely only on the information incorporated by reference or set forth in this prospectus or the applicable prospectus supplement. We have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, or any applicable prospectus supplement or post-effective amendment to the Registration Statement. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside of the United States.

We urge you to read carefully this prospectus, before deciding whether to invest in the securities being offered.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described under “*Where You Can Find More Information*.”

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the other documents we have filed with the SEC that are incorporated by reference herein contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 27A of the Securities Act of 1933, as amended (the “Securities Act”). Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this prospectus may include, for example, statements about:

- our future financial performance, including our ability to continue as a going concern;
- our plans and strategies to raise additional funding;
- the clinical results of our drug candidates;
- the likelihood of commercial success for our drug candidates;
- our plans and strategies to obtain and maintain regulatory approvals of our drug candidates;
- the size and growth potential of the markets for our drug candidates, and our ability to serve those markets, either alone or in combination with others;
- changes in the market for our drug candidates;
- expansion plans and opportunities; and
- other factors detailed under “*Risk Factors*” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q.

These forward-looking statements represent our views as of the date of this prospectus and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date.

As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include:

- our substantial dependence on the successful commercialization of our drug candidates, if approved, in the future;
- our significant net losses and net operating cash outflows;
- our ability to demonstrate the efficacy and safety of our drug candidates;
- the clinical results for our drug candidates, which may not support further development or marketing approval;
- actions of regulatory agencies, which may affect the initiation, timing, and progress of clinical trials and marketing approval;
- our ability to achieve commercial success for our drug candidates, if approved;
- our ability to obtain and maintain protection of intellectual property for our technology and drug candidates;

- our reliance on third parties to conduct research, drug development, and other services;
- our limited operating history and our ability to obtain additional funding for operations and to complete the licensing or development and commercialization of our drug candidates;
- the impact of any future epidemics, pandemics or conflicts;
- changes in applicable laws or regulations;
- the effects of inflation;
- the effects of staffing and materials shortages;
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties set forth in “*Risk Factors*” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements.

MARKET AND INDUSTRY DATA

We obtained the industry and market data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, publicly available information and research, surveys, and studies by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry and market data included in this prospectus is reliable and based on reasonable assumptions, such data involve material risks and other uncertainties and are subject to change based on various factors, including those discussed in “*Risk Factors*.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

PROSPECTUS SUMMARY

This summary highlights selected information from this prospectus and does not contain all of the information that is important to you in making an investment decision. This summary is qualified in its entirety by the more detailed information included elsewhere in this prospectus. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus and the information incorporated herein by reference. Unless the context otherwise requires, references to “we,” “us,” “our,” “the Company,” “Clene” and similar designations are intended to mean the business and operations of Clene Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage pharmaceutical company pioneering the discovery, development, and commercialization of novel clean-surfaced nanotechnology (“CSN®”) therapeutics. CSN® therapeutics are comprised of atoms of transition elements that, when assembled in nanocrystal form, possess unusually high, unique catalytic activities not present in those same elements in bulk form. These catalytic activities drive, support, and maintain beneficial metabolic and energetic cellular reactions within diseased, stressed, and damaged cells.

Our patent-protected, proprietary position affords us the potential to develop a broad and deep pipeline of novel CSN therapeutics to address a range of diseases with high impact on human health. We innovated an electro-crystal-chemistry drug development platform that draws from advances in nanotechnology, plasma and quantum physics, material science, and biochemistry. Our platform process results in nanocrystals with faceted structures and surfaces that are free of the chemical surface modifications that accompany other production methods. Many traditional methods of nanoparticle synthesis involve the unavoidable deposition of potentially toxic organic residues and stabilizing surfactants on the particle surfaces. Synthesizing stable nanocrystals that are both nontoxic and highly catalytic has overcome this significant hurdle in harnessing transition metal catalytic activity for therapeutic use. Our clean-surfaced nanocrystals exhibit catalytic activities many-fold higher than other commercially available nanoparticles, produced using various techniques, that we have comparatively evaluated.

Our development and clinical efforts are dedicated to revolutionizing the treatment of neurodegenerative diseases to restore and protect neuronal health and function. Our nanotherapeutics target cellular energy impairments that are common to many diseases and we are currently focused on addressing the high unmet medical needs in central nervous system disorders including amyotrophic lateral sclerosis (“ALS”), multiple sclerosis (“MS”), and Parkinson’s disease (“PD”). We currently have no drugs approved for commercial sale and have not generated any revenue from drug sales. We have never been profitable and have incurred operating losses in each year since inception. We generate revenue from sales of dietary supplements through our wholly owned subsidiary, dOrbital, Inc., or through an exclusive license with 4Life Research LLC (“4Life”), an international supplier of health supplements, stockholder, and related party. We anticipate these revenues to be small compared to our operating expenses and to the revenue we expect to generate from potential future sales of our drug candidates, for which we are currently conducting clinical trials.

Recent Developments of Our Clinical Programs

Amyotrophic Lateral Sclerosis

In December 2024, we announced that we recently received written guidance from the Division of Neurology 1 (“DN1”) of the U.S. Food and Drug Administration (“FDA”) regarding a potential accelerated approval pathway for CNM-Au8® in ALS. As announced previously in September 2024, we were initially advised that the data presented in our briefing package for CNM-Au8 was not adequate to support an NDA submission under the accelerated approval pathway. However, following our November 2024 meeting with DN1 and presentation of additional data and analyses, the FDA provided guidance on a potential path to meet the regulatory standard for substantial evidence of effectiveness supporting accelerated approval. The FDA recommended that we investigate whether additional data from our ongoing compassionate use Expanded Access Programs (“EAPs”) could be leveraged to substantiate the effect of CNM-Au8 on neurofilament light (“NfL”) decline. We intend to follow the FDA’s recommendation to provide data from the ongoing EAPs and believe we can address the FDA’s requests. The additional NfL biomarker collection and analyses to support NDA submission is planned to be completed during the third quarter of 2025, as summarized below:

- *NfL biomarker analyses*—Provide supportive evidence of NfL declines in participants from our ongoing FDA-authorized compassionate-use EAPs. We will meet with the FDA in the second quarter of 2025 to review and finalize our statistical analysis plan for the EAP NfL biomarker analyses.
- *Survival pharmacometric modeling*—Provide analyses of NfL and related disease-specific biomarkers linked to clinical survival benefit and clinical changes from the Phase 2 trial data.

- *Additional ALS-specific biomarkers*—Provide analyses of additional ALS-disease specific biomarkers to support the pharmacodynamic activity of CNM-Au8 for treatment of ALS.

The FDA noted that whether NfL can serve as a reasonably likely surrogate endpoint for the effects of CNM-Au8 in ALS and whether the magnitude of change observed on NfL in patients treated with CNM-Au8 is reasonably likely to predict clinical benefit for ALS would be a matter of review. In preparation for a potential NDA submission in the fourth quarter of 2025 with the accelerated approval request, we plan to commence a confirmatory Phase 3 trial, RESTORE-ALS, in the second half of 2025. The trial is designed to investigate the effects of CNM-Au8 on improved survival (primary endpoint) and delayed time to ALS clinical worsening events (secondary efficacy endpoint). We have submitted the RESTORE-ALS trial protocol to the FDA and the FDA review process is ongoing.

Multiple Sclerosis

We have initiated a second dosing cohort of REPAIR-MS, an open-label, investigator blinded Phase 2 clinical trial in non-active progressive MS patients. Enrollment concluded in January 2025 with topline results expected in mid-2025. We plan to work closely with regulatory health authorities from the FDA, European Medicines Agency and other international regulatory bodies, MS experts, and patient representatives to determine the proper path to advance CNM-Au8 into Phase 3 and potential future approval. We expect to meet with the FDA in an end of Phase 2 meeting in the third quarter of 2025.

In April 2025, we announced new evidence of remyelination and neuronal repair in MS participants following treatment with CNM-Au8 30 mg from analyses of the long-term open-label extension of the VISIONARY-MS clinical trial. The post hoc analyses identify consistent anatomical and physiologic effects within the same trial participants resulting in cognition and vision improvement for people living with MS. The analyses highlight significant and clinically meaningful improvements in cognition and visual function, supported by corresponding objective biomarkers, including advanced magnetic resonance imaging (“MRI”) diffusion tensor imaging (“DTI”) and multi-focal visual evoked potential (“mf-VEP”) assessments. Key findings from the analyses included:

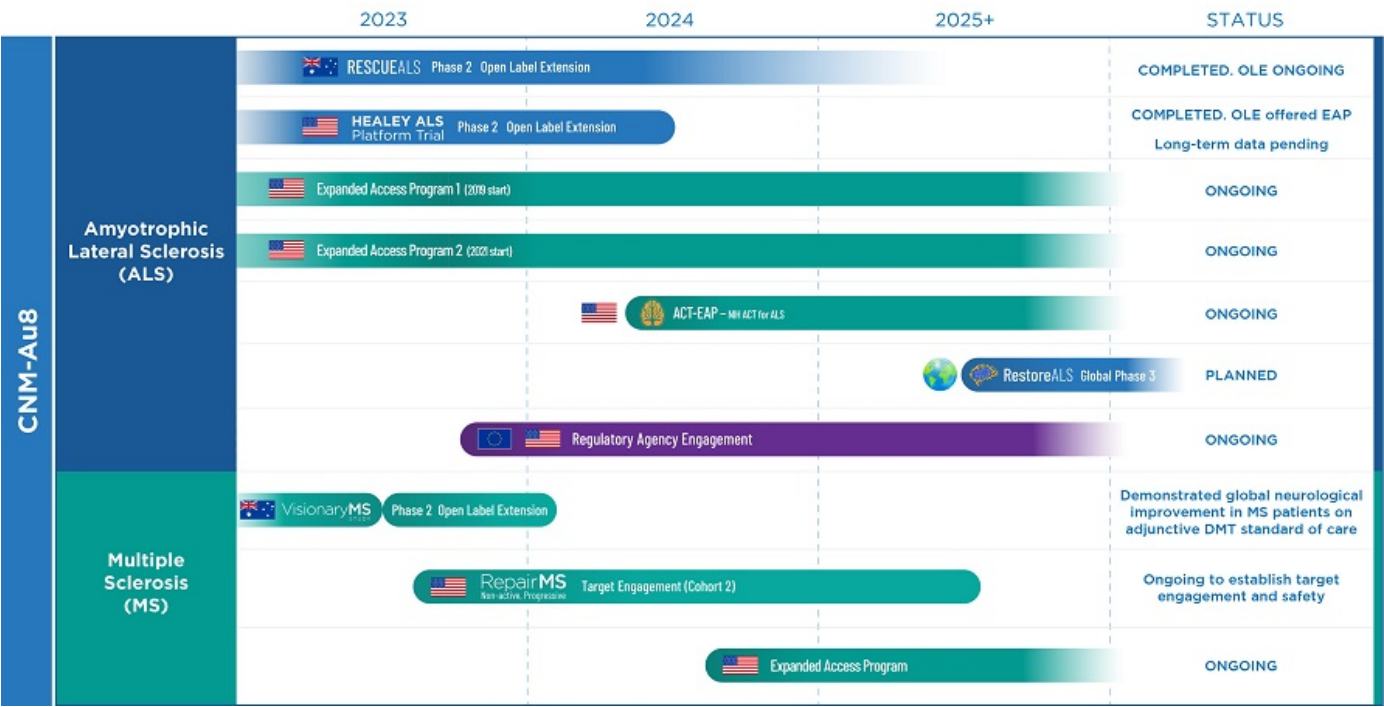
- MRI DTI metrics (axial diffusivity (“AD”) and magnetization transfer ratio (“MTR”)—structural markers associated with neuronal repair and remyelination) confirmed improvements in the brain’s neuronal structure consistent with remyelination and repair among MS participants receiving CNM-Au8; and
- mf-VEP metrics (VEP latency and amplitude—functional markers associated with remyelination and neuronal repair) confirmed improvements in the visual system and related to cognitive function among MS participants receiving CNM-Au8.

Both the low contrast letter acuity (“LCLA”) vision—a visual measure associated with vision-specific quality of life and overall MS disability—and symbol digit modality test (“SDMT”)—a benchmark for working memory and cognitive processing speed in MS—improved in CNM-Au8 participants, results that have not been previously documented in MS clinical trials of other repair candidate drugs. Importantly, these clinical improvements correlated with objective biomarker measurements including:

- 96% of participants who were LCLA responders, showing visual improvement, also demonstrated improvement in MRI DTI metrics (AD and/or MTR), evidencing repair and remyelination;
- 91% of LCLA visual responders exhibited mf-VEP improvements in latency (conduction velocity) and/or amplitude (signal strength);
 - VEP provides an objective measure of visual circuit pathway, further supporting functional recovery linked to repair and remyelination; and
- 98% of SDMT responders with improved cognition had corresponding improvements in MRI DTI metrics AD and/or MTR, substantiating that the cognitive enhancement was associated with repair and remyelination.

These results are also consistent with previous neuronal and clinical improvement observed in the double-blind period of VISIONARY-MS, while also reinforcing the long-term benefits of the novel therapeutic mechanism of CNM-Au8. CNM-Au8 supports critical repair processes within neurons and oligodendrocytes, leading to improved neurological function and remyelination, as previously documented.

The chart below reflects the growing body of evidence for CSN therapeutics from our completed and ongoing clinical programs.



Going Concern

We incurred a loss from operations \$33.1 million and \$40.5 million for the years ended December 31, 2024 and 2023, respectively. Our accumulated deficit was \$282.1 million and \$242.7 million as of December 31, 2024 and December 31, 2023, respectively. Our cash, cash equivalents, and marketable securities totaled \$12.2 million and \$35.0 million as of December 31, 2024 and December 31, 2023, respectively, and net cash used in operating activities was \$21.3 million and \$30.2 million for the years ended December 31, 2024 and 2023, respectively.

We have incurred significant losses and negative cash flows from operations since our inception. We have not generated significant revenues since our inception, and we do not anticipate generating significant revenues unless we successfully complete development and obtain regulatory approval for commercialization of a drug candidate. We expect to incur additional losses in the future, particularly as we advance the development of our clinical-stage drug candidates, continue research and development of our preclinical drug candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our senior secured convertible promissory notes (the “2024 SSCP Notes”), we are required to maintain unrestricted cash and cash equivalents of at least \$2.0 million to avoid acceleration of the full balance of the 2024 SSCP Notes. These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

To mitigate our funding needs, we plan to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as utilizing our existing at-the-market facility and equity purchase agreement and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the year ended December 31, 2024, we generated \$2.7 million of gross proceeds from our equity distribution agreement (the “ATM Agreement”), raised \$3.5 million from a registered direct offering of equity securities and an additional \$3.8 million from separate, concurrent private placements of equity securities, and raised \$10.0 million from the issuance of the 2024 SSCP Notes of which \$7.9 million was used to repay the remaining balance of our obligations under a term loan with Avenue Venture Opportunities Fund, L.P. (“Avenue”). Additionally, subsequent to December 31, 2024, we generated \$3.3 million of gross proceeds from our ATM Agreement. We have implemented cost-saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts and elimination of certain staff positions. We have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date our consolidated financial statements for the year ended December 31, 2025, were issued.

Our financial statements incorporated herein by reference have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result, our financial statements incorporated herein by reference do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

Smaller Reporting Company Status

We are a “smaller reporting company” because the market value of our stock held by non-affiliates was less than \$250 million as of June 30, 2024. We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million as of June 30 in the most recently completed fiscal year. As a smaller reporting company, we are eligible for and may take advantage of certain exemptions from various reporting requirements applicable to other public companies for as long as we continue to be a smaller reporting company, including (i) the choice of presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, (ii) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Corporate History and Information

Clene Nanomedicine, Inc. (“Clene Nanomedicine”) became a public company on December 30, 2020 (the “Closing Date”) when it completed a reverse recapitalization (the “Reverse Recapitalization”) with Tottenham Acquisition I Limited (“Tottenham”), and with Tottenham’s wholly-owned subsidiary and our predecessor, Chelsea Worldwide Inc., and Creative Worldwide Inc., a wholly-owned subsidiary of Chelsea Worldwide Inc. On the Closing Date, Chelsea Worldwide Inc. changed its name to Clene Inc. and listed its shares of common stock, par value \$0.0001 per share (“common stock”), on Nasdaq under the symbol “CLNN.”

We effected a 1-for-20 reverse stock split of our common stock beginning with the opening of trading on July 11, 2024 (the “Reverse Stock Split”). As a result, every 20 shares of common stock issued and outstanding were automatically combined and converted into 1 validly issued, fully paid and non-assessable share. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of common stock were adjusted as a result of the Reverse Stock Split, in accordance with the terms of each such security. In addition, the number of shares reserved for issuance pursuant to our Amended 2020 Stock Plan was also appropriately adjusted. All historical share and per share data for the periods presented in this prospectus, including for periods ending prior to July 11, 2024, has been adjusted to reflect the 1-for-20 Reverse Stock Split.

The mailing address for our principal executive office is 6550 South Millrock Drive, Suite G50, Salt Lake City, Utah 84121, and our telephone number is (801) 676-9695. Our website address is <https://clene.com>. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

The Offering

Under this prospectus, we may offer and sell to the public in one or more series or issuances of common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, and/or units consisting of some or all of these securities with an aggregate offering price not to exceed \$160,000,000.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should carefully consider the risks and uncertainties described under “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, which are incorporated herein by reference, together with the information contained in this prospectus and any other information that has been or will be incorporated herein by reference. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. The risk factors are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially and adversely from those anticipated in the forward-looking statements as a result of a number of factors. See “Cautionary Note Regarding Forward-Looking Statements.”

USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we will use the net proceeds from the sale of securities offered by this prospectus for expenses primarily related to general corporate purposes, including to fund the clinical development of our lead drug candidate, CNM-Au8, including for conducting our on-going and planned clinical trials and expanded access protocols; potential future commercialization efforts and future regulatory activities including preparation of regulatory filings; additional early-stage research and development activities; and for business development activities, working capital and other general corporate purposes. Any specific allocation of the net proceeds of an offering of securities to a specific purpose will be determined at the time of such offering and will be described in the related supplement to this prospectus.

The expected use of net proceeds represents our intentions based upon our present plans and business conditions. We cannot specify with certainty all of the particular uses for the net proceeds. Due to uncertainties inherent in the drug development process, it is difficult to estimate the exact amounts of the net proceeds that will be used for any particular purpose. We may use our existing cash and the future payments, if any, generated from any future collaboration agreements to fund our operations, either of which may alter the amount of net proceeds used for a particular purpose. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of clinical trials, and the timing of regulatory submissions. Accordingly, we will have broad discretion in using these net proceeds.

We intend to invest the net proceeds we receive that are not used as described above in a variety of capital preservation investments, including investment-grade, interest-bearing instruments and certificates of deposit or direct or guaranteed obligations of the U.S. government.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights and preferences of our capital stock. While we believe that the following description covers the material terms of our capital stock, the description may not contain all of the information that is important to you. We encourage you to read carefully this entire prospectus, any future related prospectus supplement and certificates of designation relating to the securities, as applicable, our amended and restated certificate of incorporation (the “certificate of incorporation”) and amended and restated bylaws (the “bylaws”) and the other documents we refer to for a more complete understanding of our capital stock. Copies of our certificate of incorporation and bylaws are incorporated by reference as exhibits to the registration statement of which this prospectus is a part. See “Where You Can Find More Information” and “Information Incorporated by Reference.”

General

We are governed by the certificate of incorporation, as amended and restated from time to time, and the Delaware General Corporation Law (“DGCL”), and the common law of the state of Delaware. The following summary of certain provisions of our securities does not purport to be complete and is subject to our amended and restated certificate of incorporation, as amended, our amended and restated bylaws and the provisions of the DGCL. Copies of our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws are incorporated by reference as Exhibits 3.1, 3.2, 3.3 and 3.4, respectively, to this prospectus

Our amended and restated certificate of incorporation authorizes a total number of shares of all classes of stock of 601,000,000 shares, consisting of (i) 600,000,000 shares of common stock, par value \$0.0001 per share, and (ii) 1,000,000 shares of preferred stock, par value \$0.0001 per share.

Common Stock

Our common stock is listed on Nasdaq under the symbol “CLNN.” The holders of our common stock are entitled to one vote for each share held on all matters to be voted on by stockholders and do not have cumulative voting rights. The holders of our common stock are entitled to receive dividends, if and when declared by our Board of Directors (the “Board”) out of funds legally available therefor. In the event of a liquidation, dissolution, or winding up of the Company, our stockholders are entitled to share ratably in all assets remaining available for distribution to them after payment of liabilities and after provision is made for each class of stock, if any, having preference over our common stock. Holders of our common stock have no preemptive or other subscription rights. Our Board is classified.

Preferred Stock

Our preferred stock is currently undesignated and no shares of preferred stock are outstanding. The Board has the authority to issue shares of preferred stock from time to time on terms it may determine, to divide shares of preferred stock into one or more series and to fix the designations, preferences, privileges and restrictions of preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series to the fullest extent permitted by the DGCL. The issuance of preferred stock could have the effect of decreasing the trading price of common stock, restricting dividends on our capital stock, diluting the voting power of the common stock, impairing the liquidation rights of our capital stock or delaying or preventing a change in control of the Company. There is no restriction on the repurchase or redemption of shares by us while there is any arrearage in the payment of dividends or sinking fund installments.

Warrants

As of the date of this prospectus, we had warrants outstanding that were exercisable into a total of 7,242,876 shares of common stock, as outlined below.

Public Warrants

The warrants originally issued by Tottenham are listed on Nasdaq under the symbol “CLNNW” (the “Public Warrants”). Each Public Warrant entitles the holder thereof to purchase one-fortieth (1/40) of one share of common stock at a price of \$230.00 per full share. We will not issue fractional shares. As a result, a Public Warrant holder must exercise warrants in multiples of forty, at a price of \$230.00 per full share, subject to adjustment, to validly exercise the warrants. The Public Warrants became exercisable upon the completion of the Reverse Recapitalization and will expire on December 30, 2025. As of the date of this prospectus, we had 4,815,000 Public Warrants outstanding exercisable into 120,375 shares of common stock. The Public Warrants are currently exercisable.

We may redeem the outstanding Public Warrants (excluding the private warrants that are part of the private units), in whole and not in part, at a price of \$0.01 per warrant:

- at any time while the warrants are exercisable;
- upon a minimum of 30 days’ prior written notice of redemption;
- if, and only if, the last sales price of our common stock equals or exceeds \$330.00 per share for any 20 trading days within a 30-trading day period ending three business days before we send the notice of redemption; and
- if, and only if, (i) there is a current registration statement in effect with respect to our common stock underlying the warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption or (ii) the warrants may be exercised on a cashless basis as set forth in the warrant agreement and such cashless exercise is exempt from registration under the Securities Act.

If the foregoing conditions are satisfied and we issue a notice of redemption, each warrant holder can exercise his, her or its warrant prior to the scheduled redemption date. However, the price of our common stock may fall below the \$330.00 trigger price as well as the \$230.00 exercise price per full share after the redemption notice is issued and not limit our ability to complete the redemption.

If we call the Public Warrants for redemption as described above, our management will have the option to require all warrant holders that wish to exercise the warrants to do so on a “cashless” basis. In such event, each warrant holder would pay the exercise price by surrendering the whole warrant for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of our warrants and the “fair market value” (as defined below) by (y) the fair market value. The “fair market value” means the average reported last sale price of our common stock for the ten trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the warrant holders. Whether we will exercise the option to require all warrant holders to exercise their warrants on a “cashless basis” will depend on a variety of factors, including the price of our common stock at the time the warrants are called for redemption, our cash needs at such time and concerns regarding dilutive share issuances.

Option Warrants

In July 2021, Chardan Capital Markets, LLC (“Chardan”) exercised a unit purchase option originally issued in connection with Tottenham’s initial public offering in August 2018 for 11,000 units, each unit consisting of one and one-tenth (1/10) shares of common stock and twenty warrants to purchase one-fortieth (1/40) of one share of common stock at an exercise price of \$230.00 per share. Chardan elected to perform a cashless or net exercise, which resulted in a net issuance of 49,166 warrants to purchase one-fortieth (1/40) of one share of common stock (the “Option Warrants”). The Option Warrants became exercisable upon issuance and are subject to the same expiration and redemption terms as the Public Warrants. As of the date of this prospectus, the Option Warrants are exercisable into 1,229 shares of common stock.

2023 Avenue Warrant

In June 2023, we issued a warrant (the “2023 Avenue Warrant”) in connection with an amendment to a loan agreement by and among the Company and our wholly owned subsidiary, Clene Nanomedicine, Inc., and Avenue and its affiliates. The 2023 Avenue Warrant became exercisable upon issuance and expires on June 30, 2028. Avenue may exercise the 2023 Avenue Warrant for cash or on a net or “cashless” basis. In the event of a change of control of the Company, the 2023 Avenue Warrant shall be automatically exchanged for the number of shares of common stock which remain exercisable thereunder immediately prior to the change of control transaction, for no payment or consideration from Avenue for such shares, and the 2023 Avenue Warrant shall be terminated. As of the date of this prospectus, the 2023 Avenue Warrant is exercisable into 150,000 shares of common stock. Upon effectiveness of an amendment to the loan agreement, dated September 30, 2024, the 2023 Avenue Warrant was amended and restated to reflect an exercise price of \$4.6014 per share. The other material terms of the 2023 Avenue Warrant remained effective as summarized herein.

Tranche A Warrants & Tranche B Warrants

In June 2023, pursuant to an underwritten public equity offering, we sold units each consisting of (i) one share of common stock, (ii) one warrant to purchase one share of common stock at an exercise price of \$22.00 per share (the “Tranche A Warrants”), and (iii) one warrant to purchase one share of common stock at an exercise price of \$30.00 per share (the “Tranche B Warrants”). The Tranche A Warrants were exercisable immediately and will expire on the earlier of (i) sixty (60) days following the date of our public announcement that the filing of a New Drug Application (“NDA”) for CNM-Au8 has been accepted by the U.S. Food and Drug Administration (“FDA”), or (ii) June 16, 2026. The Tranche B Warrants were exercisable immediately and will expire on the earlier of (i) sixty (60) days following the date of our public announcement that an NDA for CNM-Au8 has been approved by the FDA, or (ii) June 16, 2030. If we enter into or become party to a fundamental transaction (which generally includes a merger of the Company with or into another entity; the sale, lease, license, or transfer of all or substantially all of our assets; tender or exchange offers; or reclassification, reorganization, or recapitalization of our common stock), then (i) we or our successor entity shall purchase all outstanding Tranche A Warrants by paying the holders cash in an amount equal to the Black-Scholes value of the remaining unexercised portion of each Tranche A Warrant, and (ii) upon any subsequent exercise of a Tranche B Warrant, the holder shall be entitled to receive, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such fundamental transaction by a holder of the number of shares of our common stock for which the warrant is exercisable immediately prior to such fundamental transaction. As of the date of this prospectus, the Tranche A Warrants and Tranche B Warrants are exercisable into 2,500,000 and 2,500,000 shares of common stock, respectively.

2024 Pre-Funded Warrants

In October 2024, pursuant to a registered direct offering and a separate, concurrent private placement, we sold pre-funded warrants (the “2024 Pre-Funded Warrants”) with an exercise price of \$0.001 per share of common stock. The 2024 Pre-Funded Warrants are currently exercisable and will expire when exercised in full. Additionally, the 2024 Pre-Funded Warrants may be exercised on a net or “cashless” basis. In the event of a fundamental transaction, as described in the 2024 Pre-Funded Warrants and generally including any merger or consolidation, or the sale, lease, license, assignment, transfer, or other conveyance or disposition of all or substantially all of our assets, or any purchase offer, tender offer or exchange offer is completed whereby holders of our common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by holders of 50% or more of our outstanding common stock or voting power, any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property, or consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) whereby any person or group acquires 50% or more of our outstanding common stock or voting power, then the holders of the 2024 Pre-Funded Warrants will be entitled to receive upon any subsequent exercise of the 2024 Pre-Funded Warrants, at the option of the holders, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction. As of the date of this prospectus, the 2024 Pre-Funded Warrants are exercisable into 424,358 shares of common stock.

2024 Common Warrants

In October 2024, pursuant to a registered direct offering and separate, concurrent private placements, we sold warrants (the “2024 Common Warrants”) with an exercise price of \$4.82 per share of common stock. The 2024 Common Warrants are currently exercisable and expire five (5) years from the issuance date of October 1, 2024. In the event of a fundamental transaction, as described in the 2024 Common Warrants and generally including any merger or consolidation, or the sale, lease, license, assignment, transfer, or other conveyance or disposition of all or substantially all of our assets, or any purchase offer, tender offer or exchange offer is completed whereby holders of our common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by holders of 50% or more of our outstanding common stock or voting power, any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property, or consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) whereby any person or group acquires 50% or more of our outstanding common stock or voting power, then holders of the 2024 Common Warrants will be entitled to receive upon any subsequent exercise of the 2024 Common Warrants, at the option of the holders, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction. Notwithstanding anything to the contrary, in the event of a fundamental transaction, the Company or any successor entity shall, at the holder’s option, purchase the 2024 Common Warrants by paying to the holders the amount of cash equal to the Black Scholes Value (as defined in the 2024 Common Warrants) of the remaining unexercised portion of the 2024 Common Warrants on the date of the consummation of such fundamental transaction; provided, however, that, if the fundamental transaction is not within our control, including not approved by our Board of Directors, the holders shall only be entitled to receive from the Company or any successor the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the 2024 Common Warrants, that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of our common stock are given the choice to receive from among alternative forms of consideration in connection with the fundamental transaction; provided, further, that if holders of our common stock are not offered or paid any consideration in such fundamental transaction, such holders of our common stock will be deemed to have received common stock of the successor in such fundamental transaction. As of the date of this prospectus, the 2024 Common Warrants are exercisable into 1,546,914 shares of common stock.

Stock Options

As of the date of this prospectus, we had outstanding stock options to purchase 2,257,140 shares, with a weighted average exercise price of \$24.61 per share.

Restricted Stock Awards

As of the date of this prospectus, we had 37,441 outstanding and unvested rights to restricted stock awards, which were subject to time-based and market-based vesting conditions.

Contingent Earn-Outs

As of the date of this prospectus, we had outstanding and unvested earn-outs to issue 329,628 shares, which were subject to market-based and performance-based vesting conditions.

Senior Secured Convertible Promissory Notes

As of the date of this prospectus, we had outstanding senior secured convertible promissory notes (the “Notes”) in a principal amount totaling \$10.0 million which we issued to Kensington Clene 2024 LLC, 4Life Research, LLC and La Scala Investments, LLC pursuant to a note purchase agreement. At the sole election of the holder of a Note, up to 65% of the outstanding principal balance of a Note may be converted into the number of shares of our common stock, equal to the outstanding principal balance elected by the holder to be converted divided by \$5.668. Notwithstanding the foregoing, in the event that the holder of a Note declines to convert its pro rata share of outstanding principal balance, the remaining holders of the Notes may convert additional amounts, provided that no outstanding principal balance converted among all Notes exceeds \$6.5 million. The Notes expire on the earlier of: (i) the date that is 18 months following the closing date of December 20, 2024, or (ii) a “Change in Control” as described below (the “Maturity Date”). Monthly principal repayments of \$1,000,000 per month, made pro rata to the holders of the Notes, will commence on the 13-month anniversary of issuance and will continue until the Maturity Date, upon which date the remaining unpaid balance of principal together with any accrued and unpaid interest shall be due.

A Change in Control means a merger or consolidation of us with or into any other entity in which our stockholders immediately prior to the merger or consolidation do not own more than 50% of the outstanding voting power (assuming conversion of all convertible securities and the exercise of all outstanding options and warrants) of the surviving entity or the sale, lease, licensing, transfer or other disposition of all or substantially all of our the assets; provided, however, that any new issuance of capital stock to one or more third parties for the sole purpose of providing new funding or solely in connection with a public offering of stock shall not constitute a Change in Control. In the event of a Change in Control or any bankruptcy, liquidation, or other restructuring process, the holder of a Note may, at its option, (i) convert up to 65% of the outstanding principal balance of the Note into common stock, (ii) receive a total return, paid in cash, equal to 115% of the outstanding principal balance of the Note, or (iii) any combination thereof, prior to such monetization event, before any security or claim junior to the Note shall receive any proceeds from such monetization event. Events of Default under the Notes include: (i) failure to deliver the conversion shares, (ii) default in the payment of the principal of, or any other amount owing in respect of, the Notes when they become due and payable and the continuance of such default for a period of ten business days after a written notice has been given to the Company; (iii) default in the performance or observance of any covenant or agreement of the Company in the Notes or the note purchase agreement, and the continuance of such default for a period of ten business days after a written notice has been given to the Company; (iv) the failure of the Company to maintain a minimum balance of \$2.0 million in unrestricted cash; (v) the entry of a decree or order by a court adjudging the Company as bankrupt or insolvent; or approving as properly filed a petition seeking reorganization, arrangement, adjustment or composition of the Company, or appointing a receiver, liquidator, assignee, trustee or sequestrator of the Company or of any substantial part of its property, or ordering the winding-up or liquidation of its affairs, and the continuance of any such decree or order unstayed and in effect for a period of 60 calendar days; and (vi) the institution by the Company of proceedings to be adjudicated as bankrupt or insolvent, or the consent by it to the institution of bankruptcy or insolvency proceedings against it, or the filing by it of a petition or answer or consent seeking reorganization or relief, or the consent by it to the filing of any such petition or to the appointment of a receiver, liquidator, assignee, trustee or sequestrator of the Company or of any substantial part of its property, or the making by it of an assignment for the benefit of creditors.

Convertible Notes Payable

As of the date of this prospectus, we had outstanding convertible notes payable under a loan agreement with the Maryland Department of Housing and Community Development (“DHCD”) which was convertible into 62,500 shares of common stock at the discretion, but not the obligation, of DHCD at any time from December 8, 2023 through the maturity date of January 1, 2028.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides for indemnification and advancement by us of certain expenses and costs relating to claims, suits or proceedings arising from service to us or, at our request, service to other entities, as officers or directors to the maximum extent permitted by applicable law.

Dividends

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Our ability to declare dividends is limited by the terms of financing or other agreements that we have entered into. Future debt or other financing arrangements also may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our Board and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our Board may deem relevant.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent and registrar’s address is 48 Wall Street, Floor 23, New York, NY 10005.

DESCRIPTION OF DEBT SECURITIES

This section describes the general terms and provisions of our debt securities that we may issue from time to time. We may issue debt securities, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any future debt securities we may offer under this prospectus, the applicable prospectus supplement will describe the specific terms of any debt securities offered through that prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below, and to the extent the terms set forth in a prospectus supplement differ from the terms described below, the terms set forth in the prospectus supplement shall control. Unless the context requires otherwise, whenever we refer to the “indentures,” we are also referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue any senior debt securities under the senior indenture that we will enter into with the trustee named in the senior indenture. We will issue any subordinated debt securities under the subordinated indenture that we will enter into with the trustee named in the subordinated indenture. We have filed forms of these documents as exhibits to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

The indentures will be qualified under the Trust Indenture Act of 1939, as amended (the “Trust Indenture Act”). We use the term “trustee” to refer to either the trustee under the senior indenture or the trustee under the subordinated indenture, as applicable.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplement related to the debt securities that we may offer under this prospectus, as well as the complete applicable indenture that contains the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior indenture and the subordinated indenture are identical.

General

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title;
- the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;
- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, and, if so, the terms and who the depository will be;
- the maturity date;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- the terms of the subordination of any series of subordinated debt;
- the place where payments will be payable;
- restrictions on transfer, sale or other assignment, if any;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;

- the date, if any, after which, the conditions upon which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option, to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- whether the indenture will restrict our ability or the ability of our subsidiaries, if any at such time, to:
 - incur additional indebtedness;
 - issue additional securities;
 - create liens;
 - pay dividends or make distributions in respect of our capital stock or the capital stock of our subsidiaries;
 - redeem capital stock;
 - place restrictions on our subsidiaries' ability to pay dividends, make distributions or transfer assets;
 - make investments or other restricted payments;
 - sell or otherwise dispose of assets;
 - enter into sale-leaseback transactions;
 - engage in transactions with stockholders or affiliates;
 - issue or sell stock of our subsidiaries; or
 - effect a consolidation or merger;
- whether the indenture will require us to maintain any interest coverage, fixed charge, cash flow-based, asset-based or other financial ratios;
- a discussion of certain material U.S. federal income tax considerations applicable to the debt securities;
- information describing any book-entry features;
- provisions for a sinking fund purchase or other analogous fund, if any;
- the applicability of the provisions in the indenture on discharge;
- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an "original issue discount" as defined in paragraph (a) of Section 1273 of the Internal Revenue Code, as amended;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, including any additional events of default or covenants provided with respect to the debt securities, and any terms that may be required by us or advisable under applicable laws or regulations or advisable in connection with the marketing of the debt securities.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock, our preferred stock or other securities (including securities of a third party). We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock, our preferred stock or other securities (including securities of a third-party) that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indentures will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor to or acquirer of such assets must assume all of our obligations under the indentures or the debt securities, as appropriate. If the debt securities are convertible into or exchangeable for other securities of ours or securities of other entities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities that the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default Under the Indenture

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the following are events of default under the indentures with respect to any series of debt securities that we may issue:

- if we fail to pay interest when due and payable and our failure continues for 90 days and the time for payment has not been extended;
- if we fail to pay the principal, premium or sinking fund payment, if any, when due and payable at maturity, upon redemption or repurchase or otherwise, and the time for payment has not been extended;
- if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

We will describe in each applicable prospectus supplement any additional events of default relating to the relevant series of debt securities.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the trustee or the holders of not less than a majority in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the unpaid principal, premium, if any, and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity or security satisfactory to it against any loss, liability or expense. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and

- subject to its duties under the Trust Indenture Act, the trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

- the holder has given written notice to the trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the trustee or security satisfactory to it against any loss, liability or expense or to be incurred in compliance with instituting the proceeding as trustee; and
- the trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities, or other defaults that may be specified in the applicable prospectus supplement.

We will periodically file statements with the trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

Subject to the terms of the indenture for any series of debt securities that we may issue, we and the trustee may change an indenture without the consent of any holders with respect to the following specific matters:

- to fix any ambiguity, defect or inconsistency in the indenture;
- to comply with the provisions described above under “—Consolidation, Merger or Sale”;
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act;
- to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided under “Description of Debt Securities—General,” to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment hereunder by a successor trustee;
- to provide for uncertificated debt securities and to make all appropriate changes for such purpose;
- to add to our covenants such new covenants, restrictions, conditions or provisions for the benefit of the holders, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred to us in the indenture; or
- to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, subject to the terms of the indenture for any series of debt securities that we may issue or as otherwise provided in the prospectus supplement applicable to a particular series of debt securities, we and the trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

- extending the stated maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption or repurchase of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that, subject to the terms of the indenture and any limitation otherwise provided in the prospectus supplement applicable to a particular series of debt securities, we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the trustee;
- compensate and indemnify the trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, any premium, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depository named by us and identified in a prospectus supplement with respect to that series.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series. If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs.

Subject to this provision, the trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the Debt Security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

Ranking of Debt Securities

The subordinated debt securities will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture does not limit the amount of subordinated debt securities that we may issue. It also does not limit us from issuing any other secured or unsecured debt.

The senior debt securities will rank equally in right of payment to all our other senior unsecured debt. The senior indenture does not limit the amount of senior debt securities that we may issue. It also does not limit us from issuing any other secured or unsecured debt.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement, which includes this prospectus.

General

We may issue warrants for the purchase of common stock, preferred stock or debt securities, in one or more series. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from these securities.

We plan to evidence each series of warrants by warrant certificates that we will issue under a separate warrant agreement. We will enter into the warrant agreement with a warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- the number of shares of common stock purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the periods during which, and places at which, the warrants are exercisable;
- the manner of exercise;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreement and warrants may be modified;
- if applicable, a discussion of certain material U.S. federal income tax considerations of holding or exercising the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

DESCRIPTION OF UNITS

General

We may issue units comprised of common stock, preferred stock, debt securities and warrants to purchase common stock, preferred stock or debt securities in any combination. We may issue units in such amounts and in as many distinct series as we wish. This section outlines certain provisions of the units that we may issue. If we issue units, they will be issued under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. The information described in this section may not be complete in all respects and is qualified entirely by reference to the unit agreement with respect to the units of any particular series. The specific terms of any series of units offered will be described in the applicable prospectus supplement. If so described in a particular supplement, the specific terms of any series of units may differ from the general description of terms presented below. We urge you to read any prospectus supplement related to any series of units we may offer, as well as the complete unit agreement and unit certificate that contain the terms of the units. If we issue units, forms of unit agreements and unit certificates relating to such units will be incorporated by reference as exhibits to the registration statement, which includes this prospectus.

Each unit that we may issue will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. The applicable prospectus supplement may describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement;
- the price or prices at which such units will be issued;
- the applicable U.S. federal income tax considerations relating to the units;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- any other terms of the units and of the securities comprising the units.

The provisions described in this section, as well as those described under “*Description of Capital Stock*,” “*Description of Debt Securities*,” and “*Description of Warrants*” will apply to the securities included in each unit, to the extent relevant and as may be updated in any prospectus supplements. We may issue units in such amounts and in as many distinct series as we wish. This section summarizes terms of the units that apply generally to all series. Most of the financial and other specific terms of a particular series of units will be described in the applicable prospectus supplement.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, “at the market offerings,” negotiated transactions, block trades, or a combination of these methods or any other method permitted pursuant to applicable law. We may sell the securities to or through one or more underwriters or dealers (acting as principal or agent), through agents, directly to one or more purchasers through a combination of any of those methods of sale or through any other means. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed from time to time;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements will describe the terms of the offering of the securities, including, to the extent applicable:

- the name or names of the underwriters, dealers, or agents, if any;
- the purchase price of the securities or other consideration therefor, and the proceeds, if any, we will receive from the sale;
- any over-allotment or other options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts or concessions and other items constituting agents’ or underwriters’ compensation;
- any public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

At-the-Market Offerings

If we reach an agreement with an underwriter on a placement, including the number of shares of stock to be offered in the placement and any minimum price below which sales may not be made, such underwriter would agree to use its commercially reasonable efforts, consistent with its normal trading and sales practices, to try to sell such shares on such terms. Underwriters could make sales in privately negotiated transactions and/or any other method permitted by law, including sales deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act, sales made directly on Nasdaq, the existing trading market for our stock, or sales made to or through a market maker other than on an exchange. The name of any such underwriter or agent involved in the offer and sale of our stock, the amounts underwritten, and the nature of its obligations to take our stock will be described in the applicable prospectus supplement.

Underwriters and Agents

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement. Dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and compensation received by them on resale of the securities may be deemed to be underwriting discounts. If such dealers or agents were deemed to be underwriters, they may be subject to statutory liabilities under the Securities Act.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. If a dealer is used in the sale of securities, we or an underwriter will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement the name of the dealer and the terms of the transaction. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time.

We may use underwriters, dealers or agents with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, dealer or agent, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We may also designate agents to solicit offers to purchase the securities from time to time and may enter into arrangements for "at-the-market," equity line or similar transactions. We will name any agent involved in the offering and sale of securities and we will describe any commissions payable to the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, the agent will act on a best-efforts basis for the period of its appointment.

We may provide agents, underwriters and dealers with indemnification against civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents, underwriters or dealers may make with respect to these liabilities. Agents, underwriters and dealers, or their affiliates, may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

In order to facilitate the offering of the securities, any underwriters or agents, as the case may be, involved in the offering of such securities may engage in transactions that stabilize, maintain or otherwise affect the price of our securities. Specifically, the underwriters or agents, as the case may be, may over-allot in connection with the offering, creating a short position in our securities for their own account. In addition, to cover over-allotments or to stabilize the price of our securities, the underwriters or agents, as the case may be, may bid for, and purchase, such securities in the open market. Finally, in any offering of securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allotted to an underwriter or a broker-dealer for distributing such securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. The underwriters or agents, as the case may be, are not required to engage in these activities, and may end any of these activities at any time.

Any underwriters that are qualified market makers on Nasdaq may engage in passive market making transactions in the common stock on Nasdaq in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered pursuant to this prospectus will be passed upon by Holland & Knight LLP. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The financial statements of Clene Inc. as of and for the years ended December 31, 2024 and 2023 incorporated by reference in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are incorporated by reference in reliance upon the report of such firm given their authority as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a Registration Statement on Form S-3, including exhibits, under the Securities Act, with respect to the securities offered pursuant to this prospectus. This prospectus is part of the Registration Statement, but does not contain all of the information included in the Registration Statement or the exhibits. For further information with respect to us and the securities offered by this prospectus, we refer you to the Registration Statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the Registration Statement. Each of these statements is qualified in all respects by this reference.

In addition, we file annual, quarterly, and current reports, proxy statements, and other information with the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including our SEC filings, located at <https://www.sec.gov>. We also maintain a website at <https://clene.com>. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or a subsequently filed document incorporated by reference modifies or replaces that statement.

This prospectus and any accompanying prospectus supplement incorporate by reference the documents set forth below that have previously been filed with the SEC:

- our Annual Report on [Form 10-K](#) for the year ended December 31, 2024, filed with the SEC on March 24, 2025;
- our Current Reports on Form 8-K filed with the SEC on [January 30, 2025](#), [March 12, 2025](#), [March 27, 2025](#), and [April 8, 2025](#) (with respect to Item 8.01 only);
- the information specifically incorporated by reference into our Annual Report on [Form 10-K](#) for the year ended December 31, 2024 from our Definitive Proxy Statement on [Schedule 14A](#), filed with the SEC on April 8, 2025;
- the description of our common stock contained in the registration statement on [Form 8-A](#), dated December 30, 2020, filed pursuant to Section 12(b) of the Exchange Act, as amended by [Amendment No. 1 to Form 8-A](#), dated February 9, 2021.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including all such reports and other documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and other documents.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. You may request a copy of any documents incorporated by reference in this prospectus, at no cost, by writing or telephoning us at:

Clene Inc.
Attention: Investor Relations
6550 South Millrock Drive, Suite G50
Salt Lake City, Utah 84121
Telephone: 801-676-9695

Exhibits to the filings will not be sent, however, unless those exhibits have been specifically incorporated by reference in this prospectus or any accompanying prospectus supplement.



Clene Inc.

1,219,513 Shares of Common Stock

PROSPECTUS SUPPLEMENT

September 15, 2026