

PROSPECTUS



Clene Inc.

Up to 2,351,202 Shares of Common Stock

This prospectus relates to the offer and resale, from time to time by the Selling Securityholders, of the following securities: (i) up to an aggregate of 379,930 shares of our common stock, par value \$0.0001 per share ("common stock"), originally issued as part of three separate, concurrent private placements (the "Private Placements") on October 1, 2024 to certain of our existing stockholders (the "Current Investors") and certain of our directors and executive officers (the "Affiliate Investors"), (ii) up to an aggregate of 424,358 shares of common stock issuable upon the exercise of a pre-funded warrant to purchase common stock (the "Restricted Pre-Funded Warrant"), originally issued in the Private Placements to a certain Current Investor, and (iii) up to an aggregate of 1,546,914 shares of common stock issuable upon the exercise of warrants to purchase common stock (the "Restricted Warrants," and together with the Restricted Pre-Funded Warrant, the "Warrants"), originally issued in the Private Placements to the Current Investors, Affiliate Investors and an accredited and institutional investor (the "Accredited Investor," and collectively with the Current Investors and Affiliate Investors, the "Selling Securityholders").

This prospectus also includes an indeterminable number of additional shares of common stock as may be issued to prevent dilution resulting from stock splits, stock dividends or other similar transactions.

We will not receive any proceeds from the sale of shares of common stock by the Selling Securityholders pursuant to this prospectus, except with respect to amounts received by us upon exercise of the Warrants to the extent such Warrants are exercised for cash. However, we have paid, and will continue to pay, the expenses, other than underwriting discounts and commissions and certain expenses incurred by the Selling Securityholders in disposing of the common stock, associated with the sale of common stock pursuant to this prospectus.

We are registering the offer and resale of the common stock described above by the Selling Securityholders to satisfy certain registration rights we have granted. Our registration of the common stock covered by this prospectus does not mean that the Selling Securityholders will offer or sell any of the common stock. The Selling Securityholders and any of their permitted transferees may offer and sell the common stock covered by this prospectus in a number of different ways and at varying prices. Additional information on the Selling Securityholders, and the times and manner in which they may offer and sell the common stock under this prospectus, is provided under "Selling Securityholders" and "Plan of Distribution" in this prospectus.

You should read this prospectus and any additional prospectus supplement or amendment carefully before you invest in our securities.

Our common stock and public warrants are listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "CLNN" and "CLNNW," respectively. On November 20, 2024, the last reported sale price of our common stock and public warrants on Nasdaq was \$4.09 and \$0.0362, respectively.

Investing in our securities involves a high degree of risk. See "Risk Factors" section on page 10 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 November 22, 2024.

TABLE OF CONTENTS

| | Page |
|---|-------------|
| <u>ABOUT THIS PROSPECTUS</u> | 1 |
| <u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u> | 2 |
| <u>MARKET AND INDUSTRY DATA</u> | 4 |
| <u>PROSPECTUS SUMMARY</u> | 5 |
| <u>THE OFFERING</u> | 9 |
| <u>RISK FACTORS</u> | 10 |
| <u>USE OF PROCEEDS</u> | 11 |
| <u>DESCRIPTION OF SECURITIES</u> | 12 |
| <u>SELLING SECURITYHOLDERS</u> | 16 |
| <u>PLAN OF DISTRIBUTION</u> | 17 |
| <u>LEGAL MATTERS</u> | 21 |
| <u>EXPERTS</u> | 21 |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u> | 21 |
| <u>INFORMATION INCORPORATED BY REFERENCE</u> | 22 |

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, the Selling Securityholders and their permitted transferees may, from time to time, offer and sell, as applicable, the common stock, including the shares of common stock issuable upon exercise of the Warrants, through any means as described under “Plan of Distribution.” More specific terms of any shares of common stock that the Selling Securityholders and their permitted transferees offer and sell may be provided in a prospectus supplement that describes, among other things, the specific amounts and prices of the common stock being offered and the terms of the offering.

We may also provide a prospectus supplement or post-effective amendment to the Registration Statement to 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 under “Where You Can Find More Information.”

Neither we nor the Selling Securityholders have authorized anyone to provide you with any information or to make any representations other than those contained in, or incorporated by reference into, this prospectus, or any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. Neither we nor the Selling Securityholders take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the Selling Securityholders will make an offer to sell this common stock 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.

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.”

For investors outside of the United States: We have not, and the Selling Securityholders 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 the shares of common stock and the distribution of this prospectus outside of the United States.

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 inability to maintain the listing of our common stock on Nasdaq;
- 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 drug development, manufacturing 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 epidemics, pandemics, and the ongoing conflicts between Ukraine and Russia and Israel and Hamas on our clinical development, commercial, and other operations;
- 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 multiple other commercially available nanoparticles, produced using various techniques, that we have comparatively evaluated.

We have multiple drug assets currently in development and/or clinical trials for applications primarily in neurology. Our development and clinical efforts 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

On November 1, 2024, we met with the U.S. Food and Drug Administration (“FDA”) in a Type C meeting that we previously announced on September 16, 2024 and are awaiting minutes from that meeting. We are also planning to execute an international confirmatory Phase 3 trial of CNM-Au8 30 mg, RESTORE-ALS, and expect to initiate the trial in the second quarter of 2025, contingent upon the outcome of the Type C meeting and funding. We announced the following planned design of RESTORE-ALS at the 2024 Annual Northeast ALS Consortium (“NEALS”) Meeting on October 23, 2024:

- *Objective:* to investigate the effects of CNM-Au8 on survival and delayed clinical worsening events in ALS.
- *Participant criteria:* ALS diagnosis per Gold Coast criteria; symptom onset within 36 months of the screening visit; $\geq 60\%$ predicted vital capacity; TRICALS risk score of -2.5 to -6.5; screening biofluid (plasma) neurofilament light ≥ 45 pg/mL; stable background treatment (e.g. riluzone, edaravone, both).
- *Locations:* North America, Europe, Australia, and Asia/Pacific.
- *Enrollment:* approximately 561 randomized participants, 2:1 treatment allocation with approximately $n = 374$ active CNM-Au8 30 mg and $n = 187$ placebo.
- *Duration:* double-blind treatment period until 190 events accrue, with open-label extension continued until study is terminated or study drug is approved.

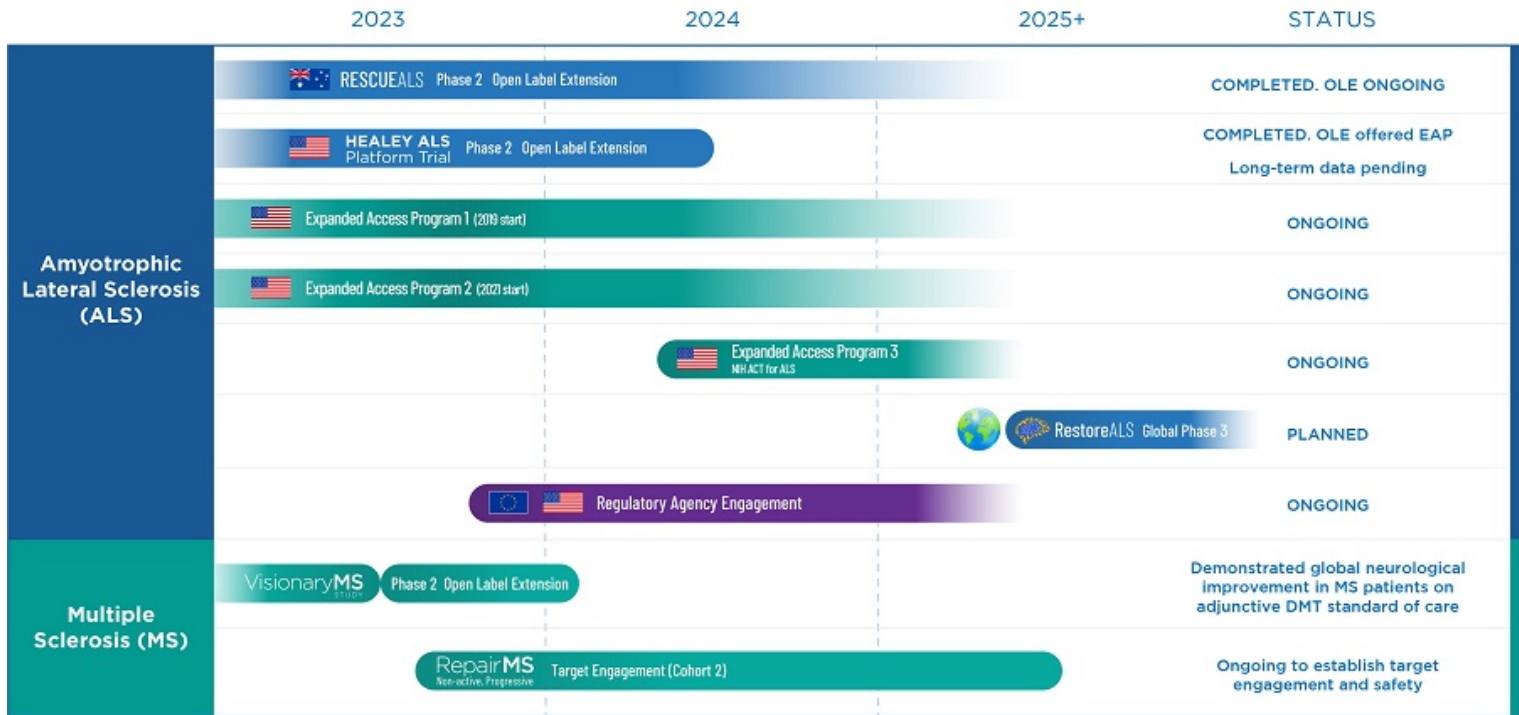
- *Primary endpoint:* delayed time to death (all-cause mortality); assumed hazard ratio of 0.625; one-sided alpha of < 0.025; power = 87% with 190 events.
- *Secondary endpoints:* (i) time to death or death equivalent (“PAV”), (ii) composite ALS clinical worsening hierarchy, (iii) joint-rank of time to death or PAV and ALSSQOL-SF change to week 72, (iv) joint-rank of time to death or PAV and ALSFRS-R change to week 72, (v) joint-rank of time to death or PAV and ROADs change to week 72, (vi) joint-rank of time to death or PAV and SVC percent change to week 72.
- *Statistical model:* covariate adjusted cox proportional hazard.

We plan to continue working closely with regulatory health authorities from the FDA, European Medicines Agency (“EMA”), ALS experts, and patient representatives to determine the proper path to support potential approval.

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. We anticipate enrollment concluding by the end of 2024 with topline results available by mid-2025. We plan to work closely with regulatory health authorities from the FDA and EMA, 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 first half of 2025.

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 of \$7.8 million and \$9.5 million for the three months ended September 30, 2024 and 2023, respectively; and \$24.4 million and \$30.6 million for the 2024 and 2023, respectively. Our accumulated deficit was \$268.6 million and \$242.7 million as of September 30, 2024 and December 31, 2023, respectively. Our cash, cash equivalents, and marketable securities totaled \$14.6 million and \$35.0 million as of September 30, 2024 and December 31, 2023, respectively, and net cash used in operating activities was \$16.5 million and \$23.0 million for the 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 term loan with Avenue Venture Opportunities Fund, L.P. (“Avenue”), we are required to maintain unrestricted cash and cash equivalents of at least \$5.0 million to avoid acceleration of the full balance of the loan. 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 three months ended September 30, 2024, we generated \$2.1 million of gross proceeds from our equity distribution agreement and subsequent to September 30, 2024, we have 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. 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 the condensed consolidated financial statements for the quarter ended September 30, 2024, 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

| | |
|--|--|
| Shares of common stock offered by the Selling Securityholders | 379,930 shares of common stock, 424,358 shares of common stock issuable upon the exercise of the Restricted Pre-Funded Warrant at an exercise price of \$0.001 per share and 1,546,914 shares of common stock issuable upon the exercise of the Restricted Warrants at an exercise price of \$4.82 per share. |
| Shares of common stock outstanding immediately after this offering prior to exercise of all Warrants | 8,359,656 shares of common stock, based on total shares outstanding as of November 20, 2024. |
| Use of proceeds | All shares of common stock offered and sold by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective accounts. We will not receive any proceeds from the sale of shares of common stock by the Selling Securityholders pursuant to this prospectus, except with respect to amounts received by us upon exercise of the Warrants to the extent such Warrants are exercised for cash. See “Use of Proceeds” for additional information. |
| Risk Factors | Any investment in the common stock offered hereby is speculative and involves a high degree of risk. You should read carefully the information set forth in “Risk Factors” and other information included elsewhere in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock. |
| Nasdaq Capital Market Symbol | “CLNN” |

The number of shares of common stock outstanding immediately after this offering is based on 7,979,726 shares of common stock outstanding as of November 20, 2024, and excludes the following:

- 1,914,795 shares of common stock issuable upon exercise of stock options outstanding as of November 20, 2024, with a weighted-average exercise price of \$28.27 per share;
- 611,994 shares of common stock reserved as of November 20, 2024, for future grant under our Amended 2020 Stock Plan;
- 7,242,876 shares of common stock issuable upon exercise of warrants and pre-funded warrants outstanding as of November 20, 2024 with a weighted-average exercise price of \$22.94 per share;
- 37,441 shares of common stock issuable upon vesting of rights to restricted stock awards and restricted stock units outstanding as of November 20, 2024;
- 329,628 shares of common stock issuable upon vesting of earn-out shares outstanding as of November 20, 2024; and
- 62,500 shares of common stock issuable upon conversion of our convertible notes payable outstanding as of November 20, 2024.

Except as otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options, warrants or pre-funded warrants; vesting of restricted stock awards, restricted stock units or earn-out shares; 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 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

All of the shares of common stock offered by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective accounts. We will not receive any proceeds from the sale of shares of common stock by the Selling Securityholders pursuant to this prospectus, except with respect to amounts received by us upon exercise of the Warrants to the extent such Warrants are exercised for cash. If the Warrants are exercised in full for cash, we would receive \$7.5 million in gross proceeds, and intend to use any proceeds received from the exercise of the Warrants to meet general working capital needs. There is no assurance that the holders of the Warrants will elect to exercise any or all of such Warrants. To the extent that the Warrants are exercised on a net or “cashless” basis, the amount of cash we would receive from the exercise of the Warrants will decrease.

We have paid, and will continue to pay, all other costs, fees and expenses incurred in effecting the registration of the common stock covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees and professional fees and expenses. The Selling Securityholders will pay any underwriting fees, discounts, selling commissions, stock transfer taxes and certain legal expenses incurred by the Selling Securityholders when disposing of their common stock.

DESCRIPTION OF SECURITIES

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." All historical share and per share data in this section has been adjusted to reflect the 1-for-20 Reverse Stock Split.

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, our amended and restated bylaws and the provisions of the DGCL. Copies of our amended and restated certificate of incorporation or 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 us. 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.

Restricted Pre-Funded Warrant

The Restricted Pre-Funded Warrant has an exercise price of \$0.001 per share of common stock, is currently exercisable and will expire when exercised in full. Additionally, the holder may elect to exercise the Restricted Pre-Funded Warrant through a “cashless exercise,” in which case the holder would receive upon such exercise the net number of underlying shares determined according to the formula set forth in the Restricted Pre-Funded Warrant. No fractional shares will be issued in connection with the exercise of the Restricted Pre-Funded Warrant. In lieu of fractional shares, the Company will, at its election, either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share. A holder will not have the right to exercise any portion of the Restricted Pre-Funded Warrant if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Registered Pre-Funded Warrant. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

In the event of a fundamental transaction, as described in the Registered Pre-Funded Warrant 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 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, or any reclassification, reorganization, recapitalization, spin-off, merger or other business combination whereby any person or group acquires 50% or more of our outstanding common stock or voting power (a “Fundamental Transaction”), then the holder of the Registered Pre-Funded Warrant will be entitled to receive upon any subsequent exercise of the Registered Pre-Funded Warrant, 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 as a result of such Fundamental Transaction.

Except as otherwise provided in the Registered Pre-Funded Warrant or by virtue of such holder’s ownership of shares of our common stock, the holder of the Registered Pre-Funded Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Registered Pre-Funded Warrant.

Restricted Warrants

The Restricted Warrants have an exercise price of \$4.82 per share of common stock, are currently exercisable and expire five (5) years from the issuance date of October 1, 2024. If there is no effective registration statement registering the underlying shares, or the prospectus contained therein is not available for the resale of such underlying shares, then the holders may exercise the Restricted Warrants by means of a “cashless exercise,” in which case the holder would receive upon such exercise the net number of underlying determined according to the formula set forth in the Restricted Warrant. No fractional shares will be issued in connection with the exercise of a Restricted Warrant. In lieu of fractional shares, the Company will, at its election, either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share. A holder will not have the right to exercise any portion of the Restricted Warrant if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Restricted Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

In the event of a fundamental transaction, as described in the Restricted Warrant 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 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, or any reclassification, reorganization, recapitalization, spin-off, merger or other business combination whereby any person or group acquires 50% or more of our outstanding common stock or voting power, then holders of the Restricted Warrants will be entitled to receive upon any subsequent exercise of the Restricted Warrants, 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 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 Restricted Warrant by paying to the holder the amount of cash equal to the Black Scholes Value (as defined in the Restricted Warrant) of the remaining unexercised portion of the Restricted Warrant 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 holder 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 Restricted Warrant, 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.

Except as otherwise provided in the Restricted Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Restricted Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Restricted Warrant.

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.

Avenue Warrant

In June 2023, we issued a warrant (the “New 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 New Avenue Warrant became exercisable upon issuance and expires on June 30, 2028. Avenue may exercise the New Avenue Warrant for cash or on a net or “cashless” basis. In the event of a change of control of the Company, the New 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 New Avenue Warrant shall be terminated. As of the date of this prospectus, the New Avenue Warrant is exercisable into 150,000 shares of common stock. Upon effectiveness of an amendment dated September 30, 2024, the New Avenue Warrant was amended and restated to reflect an exercise price of \$4.6014 per share. The other material terms of the New 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.

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.

SELLING SECURITYHOLDERS

This prospectus relates to the offer and resale, from time to time by the Selling Securityholders of the following securities: (i) up to an aggregate of 379,930 shares of common stock, originally issued in the Private Placements to the Current Investors and Affiliate Investors, (ii) up to an aggregate of 424,358 shares of common stock issuable upon the exercise of the Restricted Pre-Funded Warrant, originally issued in the Private Placements to a certain Current Investor, and (iii) up to an aggregate of 1,546,914 shares of common stock issuable upon the exercise of the Restricted Warrants, originally issued in the Private Placements to the Current Investors, Affiliate Investors and Accredited Investor. When we refer to the “Selling Securityholders” in this prospectus, we mean the persons listed in the table below, and the pledgees, donees, transferees, assignees, successors, designees and others who later come to hold any of the Selling Securityholder’s interest in the common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, information concerning the shares of common stock that may be offered from time to time by the Selling Securityholders. The Selling Securityholders are not obligated to exercise the Warrants nor sell any of the shares of common stock received upon exercise of the Warrants and offered by this prospectus. The Selling Securityholders may also offer and sell less than the number of shares of common stock indicated. The Selling Securityholders are not making any representation that any shares of common stock covered by this prospectus will or will not be offered for sale.

The number of shares of common stock and percentages of beneficial ownership set forth below are based on 7,979,726 shares of common stock issued and outstanding as of the date of this prospectus, and assumes the full exercise of the Restricted Pre-Funded Warrant and Restricted Warrants for 424,358 and 1,546,914 shares of common stock, respectively.

| Name of Selling Securityholder | Shares Beneficially Owned Prior to the Offering | | Shares Being Offered | Shares Beneficially Owned After the Offering | |
|---|---|-------|----------------------|--|-------|
| | Shares | % | | Shares | % |
| SymBiosis II, LLC ⁽¹⁾ | 2,249,661 | 19.9% | 848,716 | 1,400,945 | 15.4% |
| Armistice Capital Master Fund Ltd. | 742,626 | 8.5% | 742,626 | — | — |
| Kensington Clene 2021, LLC ⁽²⁾ | 719,622 | 8.6% | 318,268 | 401,354 | 4.7% |
| David J. Matlin ⁽³⁾ | 723,311 | 8.8% | 184,614 | 538,697 | 6.3% |
| Jeff Greenblatt | 257,388 | 3.2% | 57,288 | 200,100 | 2.4% |
| Spring Creek Holdings LLC | 67,434 | * | 42,434 | 25,000 | * |
| Chris Dewey | 117,369 | 1.5% | 42,434 | 74,935 | * |
| Mark Mortenson ⁽⁴⁾ | 124,742 | 1.5% | 41,024 | 83,718 | * |
| Peter Schoels | 21,216 | * | 21,216 | — | — |
| Robert Etherington ⁽⁵⁾ | 161,452 | 2.0% | 20,000 | 141,452 | 1.7% |
| Alessandro P. Dinello Living Trust | 16,974 | * | 16,974 | — | — |
| Neil Wessan | 10,608 | * | 10,608 | — | — |
| Joseph Mannello | 19,318 | * | 5,000 | 14,318 | * |
| Total Shares | 5,231,721 | | 2,351,202 | 2,880,519 | |

* Less than 1% of our total outstanding shares on an as converted basis.

- (1) Based solely on information contained in the Schedule 13G/A filed with the SEC on October 10, 2024 reporting beneficial ownership of Chidozie Ugwumba. Mr. Ugwumba has sole voting power and sole dispositive power over 2,249,661 shares of our Common Stock held by SymBiosis II, LLC, which includes 1,598,716 shares subject to warrants exercisable within 60 days of November 22, 2024. The warrants contain provisions preventing their exercise if such exercise would result in the holder obtaining greater than 19.99% of the Company’s voting securities. However, the amount reported in column 2 herein represents the number of shares of Common Stock that would be issuable upon exercise of the warrants in full, and does not give effect to the blocking provisions. The registered address for SymBiosis II, LLC is 609 SW 8th St., Suite 510, Bentonville, AR 72712.
- (2) Kensington Clene 2021, LLC owns and has shared voting power over 719,622 shares of our Common Stock, which includes 398,571 shares subject to warrants exercisable within 60 days of November 22, 2024. The shares owned by Kensington Clene 2021, LLC may also be deemed to be beneficially owned by Alison H. Mosca, an independent director of the Company, by reason of her service as sole Manager of Kensington Clene 2021, LLC. The registered address for Kensington Clene 2021, LLC is c/o Kensington Capital Holdings, LLC, 26 Patriot Place, Suite 301, Foxboro, MA 02035.
- (3) Mr. Matlin is an independent director of the Company.
- (4) Mr. Mortenson is the Chief Science Officer of the Company.
- (5) Mr. Etherington is the President, Chief Executive Officer and a director of the Company.

Relationship with the Selling Securityholders

In addition to the relationships described above, on September 30, 2024, we entered into securities purchase agreements with the Accredited Investor, the Current Investors and the Affiliate Investors, in connection with which we issued: (i) up to an aggregate of 379,930 shares of common stock, (ii) the Restricted Pre-Funded Warrant, and (iii) the Restricted Warrants. Additionally, we issued: (i) 725,000 shares of our common stock, and (ii) pre-funded warrants to purchase up to 17,626 shares of common stock to the Accredited Investor pursuant to a prospectus supplement and a securities purchase agreement.

PLAN OF DISTRIBUTION

We are registering the offer and resale by the Selling Securityholders of (i) up to an aggregate of 379,930 shares of common stock, (ii) up to an aggregate of 424,358 shares of common stock issuable upon the exercise of the Restricted Pre-Funded Warrant, and (iii) up to an aggregate of 1,546,914 shares of common stock issuable upon the exercise of the Restricted Warrants. We are required to pay all fees and expenses incident to the registration of the shares of common stock that may be offered and sold pursuant to this prospectus.

The shares of common stock beneficially owned by the Selling Securityholders covered by this prospectus may be offered and sold from time to time by the Selling Securityholders. The term "Selling Securityholders" includes donees, pledgees, transferees or other successors in interest selling securities received after the date of this prospectus from a Selling Securityholders as a gift, pledge, partnership distribution or other transfer. The Selling Securityholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then-current market price or in negotiated transactions. The Selling Securityholders may sell their shares by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution in accordance with the rules of Nasdaq;
- through trading plans entered into by a Selling Securityholders pursuant to Rule 10b5-1 under the Exchange Act that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- through one or more underwritten offerings on a firm commitment or best efforts basis;
- settlement of short sales entered into after the date of this prospectus;
- agreements with broker-dealers to sell a specified number of the securities at a stipulated price per share or warrant;
- in "at the market" offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- directly to purchasers, including through a specific bidding, auction or other process or in privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- through a combination of any of the above methods of sale; or
- any other method permitted pursuant to applicable law.

In addition, a Selling Securityholders that is an entity may elect to make a pro rata in-kind distribution of securities to its members, partners or stockholders pursuant to the Registration Statement of which this prospectus is a part by delivering a prospectus with a plan of distribution. Such members, partners or stockholders would thereby receive freely tradeable securities pursuant to the distribution through a registration statement. To the extent a distributee is an affiliate of ours (or to the extent otherwise required by law), we may file a prospectus supplement in order to permit the distributees to use the prospectus to resell the securities acquired in the distribution.

There can be no assurance that the Selling Securityholders will sell all or any of the securities offered by this prospectus. In addition, the Selling Securityholders may also sell securities under Rule 144 under the Securities Act, if available, or in other transactions exempt from registration, rather than under this prospectus. The Selling Securityholders have the sole and absolute discretion not to accept any purchase offer or make any sale of securities if they deem the purchase price to be unsatisfactory at any particular time.

The Selling Securityholders may also transfer the securities in other circumstances, in which case the transferees, pledgees or other successors-in-interest will be the selling beneficial owners for purposes of this prospectus. Upon being notified by a Selling Securityholders that a donee, pledgee, transferee, or other successor-in-interest intends to sell our securities, we will, to the extent required, promptly file a supplement to this prospectus to name specifically such person as a selling stockholder.

With respect to a particular offering of the securities held by the Selling Securityholders, to the extent required, an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the Registration Statement of which this prospectus is part, will be prepared and will set forth the following information:

- the specific securities to be offered and sold;
- the name of the selling securityholders;
- the respective purchase prices and public offering prices, the proceeds to be received from the sale, if any, and other material terms of the offering;
- settlement of short sales entered into after the date of this prospectus;
- the names of any participating agents, broker-dealers or underwriters; and
- any applicable commissions, discounts, concessions and other items constituting compensation from the selling securityholders.

In connection with distributions of the securities or otherwise, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the securities in the course of hedging the positions they assume with Selling Securityholders. The Selling Securityholders may also sell the securities short and redeliver the securities to close out such short positions. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Selling Securityholders may also pledge securities to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged securities pursuant to this prospectus (as supplemented or amended to reflect such transaction).

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.

The Selling Securityholders may solicit offers to purchase the securities directly from, and it may sell such securities directly to, institutional investors or others. In this case, no underwriters or agents would be involved. The terms of any of those sales, including the terms of any bidding or auction process, if utilized, will be described in the applicable prospectus supplement.

It is possible that one or more underwriters may make a market in our securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for our securities.

The Selling Securityholders may authorize underwriters, broker-dealers or agents to solicit offers by certain purchasers to purchase the securities at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we or the Selling Securityholders pay for solicitation of these contracts.

A Selling Securityholders may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by the Selling Securityholders or borrowed from the Selling Securityholders or others to settle those sales or to close out any related open borrowings of stock and may use securities received from the Selling Securityholders in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment). In addition, the Selling Securityholders may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

In effecting sales, broker-dealers or agents engaged by the Selling Securityholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the Selling Securityholders in amounts to be negotiated immediately prior to the sale.

In compliance with the guidelines of the Financial Industry Regulatory Authority (“FINRA”), the aggregate maximum discount, commission, fees or other items constituting underwriting compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of the gross proceeds of any offering pursuant to this prospectus and any applicable prospectus supplement.

If at the time of any offering made under this prospectus a member of FINRA participating in the offering has a “conflict of interest” as defined in FINRA Rule 5121 (“Rule 5121”), that offering will be conducted in accordance with the relevant provisions of Rule 5121.

To our knowledge, there are currently no plans, arrangements or understandings between the Selling Securityholders and any broker-dealer or agent regarding the sale of the securities by the Selling Securityholders. Upon our notification by the Selling Securityholders that any material arrangement has been entered into with an underwriter or broker-dealer for the sale of securities through a block trade, special offering, exchange distribution, secondary distribution or a purchase by an underwriter or broker-dealer, we will file, if required by applicable law or regulation, a supplement to this prospectus pursuant to Rule 424(b) under the Securities Act disclosing certain material information relating to such underwriter or broker-dealer and such offering.

Underwriters, broker-dealers or agents may facilitate the marketing of an offering online directly or through one of their affiliates. In those cases, prospective investors may view offering terms and a prospectus online and, depending upon the particular underwriter, broker-dealer or agent, place orders online or through their financial advisors.

In offering the securities covered by this prospectus, the Selling Securityholders and any underwriters, broker-dealers or agents who execute sales for the Selling Securityholders may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. Any discounts, commissions, concessions or profit they earn on any resale of those securities may be underwriting discounts and commissions under the Securities Act.

The underwriters, broker-dealers and agents may engage in transactions with us or the Selling Securityholders, or perform services for us or the Selling Securityholders, in the ordinary course of business.

In order to comply with the securities laws of certain states, if applicable, the securities must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

The Selling Securityholders and any other persons participating in the sale or distribution of the securities will be subject to applicable provisions of the Securities Act and the Exchange Act, and the rules and regulations thereunder, including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of purchases and sales of any of the securities by, the Selling Securityholders or any other person, which limitations may affect the marketability of the shares of the securities.

We will make copies of this prospectus available to the Selling Securityholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Securityholders may indemnify any agent, broker-dealer or underwriter that participates in transactions involving the sale of the securities against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the Selling Securityholders against certain liabilities, including certain liabilities under the Securities Act, the Exchange Act or other federal or state law. Agents, broker-dealers and underwriters may be entitled to indemnification by us and the Selling Securityholders against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents, broker-dealers or underwriters may be required to make in respect thereof.

LEGAL MATTERS

The validity of the securities offered pursuant to this prospectus will be passed upon by Holland & Knight LLP.

EXPERTS

The financial statements of Clene Inc. as of and for the years ended December 31, 2023 and 2022 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 by the Selling Securityholders 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 the Selling Securityholders pursuant to 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 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, 2023, filed with the SEC on March 13, 2024;
- our Quarterly Reports on Form 10-Q for the quarter ended [March 31, 2024](#), filed with the SEC on May 8, 2024, the quarter ended [June 30, 2024](#), filed with the SEC on August 7, 2024, and the quarter ended [September 30, 2024](#), filed with the SEC on November 13, 2024;
- our Current Reports on Form 8-K filed with the SEC on [January 8, 2024](#) (with respect to Item 8.01 only), [January 31, 2024](#), [February 22, 2024](#) (with respect to Item 8.01 only), [February 29, 2024](#) (with respect to Item 8.01 only), [April 9, 2024](#), [April 16, 2024](#) (with respect to Item 8.01 only), [April 26, 2024](#), [May 30, 2024](#), [June 18, 2024](#) (with respect to Item 8.01 only), [July 9, 2024](#) (with respect to Item 3.03 and Item 5.03 only), [July 11, 2024](#), [July 26, 2024](#), [August 6, 2024](#) (with respect to Item 8.01 only), [September 16, 2024](#), [September 30, 2024](#) (first of two reports filed on September 30, 2024), and [September 30, 2024](#) (second of two reports filed on September 30, 2024);
- the information specifically incorporated by reference into our Annual Report on [Form 10-K](#) for the year ended December 31, 2023 from our Definitive Proxy Statement on [Schedule 14A](#), filed with the SEC on April 16, 2024; and
- 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, 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.



Clene Inc.

Up to 2,351,202 Shares of Common Stock

PROSPECTUS

November 22, 2024