UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 3, 2024

CLENE INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39834**	**85-2828339**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6550 South Millrock Drive, Suite G50 **Salt Lake City, Utah**	**84121**
(Address of principal executive offices)	(Zip Code)

(801) 676-9695

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	CLNN	The Nasdaq Capital Market
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

Previously, on October 5, 2023, Clene Inc. and its wholly owned subsidiary, Clene Nanomedicine, Inc. (together with Clene Inc. and its other subsidiaries, the "Company") announced a four-year, $45.1 million grant ("the NIH Grant") from the National Institute of Health ("NIH") to the Company, in collaboration with Colombia University ("Colombia"), the prime awardee, and Synapticure, a neurology specialty health clinic. The NIH Grant will support an Expanded Access Program (the "NIH EAP") for CNM-Au8 treatment of amyotrophic lateral sclerosis ("ALS"), and was awarded under the Accelerating Access to Critical Therapies for ALS Act. On April 3, 2024, the Company entered into a grant subaward agreement (the "Subaward") with Colombia pursuant to the NIH Grant.

The Subaward includes reimbursement of Company expenses for the NIH EAP in an amount up to $7.3 million during the period from September 25, 2023 to August 31, 2024. Disbursement of funds for the NIH EAP will be paid to the Company based on the Company's submission of invoices to Colombia for reimbursement on a monthly or quarterly basis.

Of the $45.1 million total award, subawards to the Company under the NIH Grant may total up to $30.9 million in aggregate, inclusive of the Subaward, and may extend to August 31, 2027 and will be governed by future agreements or addendums.

Either Colombia or the Company may terminate the Subaward with 30 days written notice. Notwithstanding, if NIH terminates the NIH Grant, Colombia will terminate the Subaward in accordance with the NIH requirements.

In the performance of the Subaward, the Company may use background intellectual property, which it developed at private expense prior to the Subaward, including certain inventions and related technical data (the "Background IP"). However, the Company (i) does not and will not grant any licenses to Colombia or the U.S. Government in the Background IP, either express or implied; and (ii) none of the Background IP or any improvements thereto shall be considered an invention made in the performance of the Subaward. The Company is not required to deliver any Background IP or any other proprietary data under the Subaward until and unless the recipient agrees to safeguards for the protection of the confidentiality of the data that are satisfactory to the Company.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
10.1	FDP Cost Reimbursement Subaward, dated April 3, 2024, by and between Clene Nanomedicine, Inc. and the Trustees of Colombia University in the City of New York.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CLENE INC.

Date: April 9, 2024

By: /s/ Robert Etherington
Robert Etherington
President and Chief Executive Officer

SAPO: G18548 & G18549

FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institute of Health (NIH)	
Pass-Through Entity (PTE): The Trustees of Colombia University in the City of New York	**Subrecipient:** Clene Nanomedicine Inc
PTE PI: Jinsy Andrews	Sub PI: Benjamin Greenberg
PTE Federal Award No: 1U01NS136023-01	Subaward No: 2(GG011355-01)
Project Title: Intermediate-sized Expanded Access Protocol for CNM-Au8 in Amyotrophic Lateral Sclerosis (ALS)	
Subaward Budget Period: Start: 09/25/2023 End: 08/31/2024	Amount Funded This Action (USD): $7348370
Estimated Period of Performance: Start: 09/25/2023 End: 08/31/2027	Incrementally Estimated Total (USD): $30895644

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2. Subrecipient shall submit invoices not more often that monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.

3. A final statement of cumulative costs incurred, including cost sharing, market "FINAL," must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after each Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.

4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.

5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.

6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Administrative Contact and the Subrecipient's Administrative Contact show in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.

7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Administrative Contact, as show in Attachment 3B.

8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9. Either party may terminate this Subaward within 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with the Awarding Agency requirements. PTE notice shall be directed to the Administrative Contact, and Subrecipient notice shall be directed to the Administrative Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.

10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Word in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
/s/ William J Berger	4/3/2024	/s/ Rob Etherington	4/3/2024
Name: William J Berger	Date	Name: Rob Etherington	Date
Title: Assistant Vice President		Title: CEO, Clene Inc.	

Attachment 1
Certifications and Assurances

[Omitted pursuant to Regulation S-K, Item 601(a)(5). We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.]

Attachment 2

Federal Award Terms and Conditions

Subaward Number
2(GG011355-01)

Required Data Elements

The data elements required by Uniform Guidance are incorporated in the attached Federal Award.

Awarding Agency Institute (If Applicable)

Federal Award Issue Date	FAIN	Assistance Listing No.

Assistance Listing Program Title (ALTP)

Key Personnel Per NOA

This Subaward Is:

☒ Research & Development ☒ Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website: http://grants.nih.gov/policy/notices.htm
2. 2 CFR 200 and 45 CFR Part 75.
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at: http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at: https://www.nsf.gov/awards/managing/rtc.jsp
   a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Financial Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
   b. Any payment mechanism and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
   c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
   d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
   e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:
Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in the General Terms and Conditions 1-4 above.
No additional requirements

Data Rights:
Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of an only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:
Subrecipient Grants to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):
Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: NIH - 42 CFR Part 50 Subpart F

Subrecipient shall report any financial conflict of interest to PTE's Administration Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☐ No Human or Vertebrate Animals

☒ Human Subjects **IRB** Upon Request

☐ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the Administrative Contact as required above:

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One) Human subjects data will not be addressed in this agreement

This section left intentionally blank

NIH Terms and Conditions

The Clinical Trial Indicator in Section IV of the PTE's NOA is stated as: Yes
The work being conducted by this subrecipient per this agreement is a clinical trial.

Multiple PIs (MPI)

This subaward is subject to an MPI Leadership Plan. Both parties will follow the finalized MPI Leadership Plan.
The MPI plan is attached as part of Attachment 6.

Certificate of Confidentiality:

The Parties agree that this research funded in whole or in part by the National Institutes of Health ("NIH"), is subject to NIH Policy NOT-OD-17-109 (the "Policy") and therefore is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") should the conditions outlined within the Policy apply. Accordingly, the subrecipients who collect or receive identifiable, sensitive information are is required to adhere to the Policy and protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

Additional Terms

This Subaward supersedes all prior agreements, terms, conditions, and understandings, whether oral or written.

Pursuant to 2 C.F.R. § 315(c) the provisions of 37 C.F.R. § 401.14, Standard Patent Rights Clause, apply to this Subaward except that in that clause the term "Contractor" shall mean "Subrecipient."
In the performance of this Subaward, Subrecipient may use background intellectual property, which it developed at private expense prior to the Subaward, including the inventions listed in Attachment Six hereto and related technical data (the "Background IP"). However, Subrecipient (1) does not and will not grant any licenses to the PTE or the Government in the Background IP, either express or implied; and (2) none of the inventions listed in Attachment Six or any improvements thereto shall be considered an invention made in the performance of the Subaward under 37 C.F.R. § 401.14 (i.e., a "Subject Invention"). Subrecipient is not required to deliver any Background IP or any other proprietary data hereunder until and unless the recipient agrees to safeguards for the protection of the confidentiality of the data that are satisfactory to Subrecipient.

Attachment 3A
Research Subaward Agreement
Pass-Through Entity (PTE) Contacts

[Omitted pursuant to Regulation S-K, Item 601(a)(5). We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.]

Attachment 3B
Research Subaward Agreement
Subrecipient Contacts

[Omitted pursuant to Regulation S-K, Item 601(a)(5). We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.]

Attachment 4
Reporting and Prior Approval Terms

[Omitted pursuant to Regulation S-K, Item 601(a)(5). We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.]

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

[Omitted pursuant to Regulation S-K, Item 601(a)(5). We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.]

Attachment 6
Notice of Award (NOA) and any additional documents

[Omitted pursuant to Regulation S-K, Item 601(a)(5). We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.]