

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

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2026

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-39834

CLENE INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

85-2828339

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

6550 South Millrock Drive, Suite G50
Salt Lake City, Utah

(Address of principal executive offices)

84121

(Zip Code)

(801) 676-9695

(Registrant's telephone number, including area code)

N/A

(Former name, former address, and former fiscal year, if changed since last report)

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

Title of each class

Common Stock, \$0.0001 par value

Trading Symbol(s)

CLNN

Name of each exchange on which registered

The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer

☐

Accelerated filer

☐

Non-accelerated filer

☒

Smaller reporting company

☒

Emerging growth company

☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's common stock as of August 11, 2026 was 12,848,513.

CLENE INC.
Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2026

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this Quarterly Report on Form 10-Q (“Quarterly Report”) may constitute “forward-looking statements” for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Quarterly Report 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
- any other statements that address events or developments that we intend or believe will or may occur in the future.

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

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

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

- changes in applicable laws or regulations;
- the effects of inflation;
- the effects of staffing and materials shortages;
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties set forth in the section entitled “*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 Quarterly Report, 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

CLENE INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except share and per share amounts) (Unaudited)

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,671	\$ 5,189
Accounts receivable	43	—
Inventory	37	37
Prepaid expenses and other current assets	5,163	3,751
Total current assets	14,914	8,977
Restricted cash	58	58
Operating lease right-of-use assets	2,753	3,073
Property and equipment, net	5,316	6,023
TOTAL ASSETS	\$ 23,041	\$ 18,131
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,142	\$ 892
Accrued liabilities	2,482	5,002
Operating lease obligations, current portion	815	808
Notes payable, current portion	413	1,696
Convertible notes payable, current portion	—	2,378
Total current liabilities	4,852	10,776
Operating lease obligations, net of current portion	2,805	3,250
Notes payable, net of current portion	5,374	3,741
Convertible notes payable, net of current portion	12,937	9,800
Common stock warrant liabilities	16,137	5,063
Derivative liabilities	5,713	3,093
TOTAL LIABILITIES	47,818	35,723
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock, \$0.0001 par value: 600,000,000 shares authorized; 12,778,307 and 10,849,974 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	304,825	290,531
Accumulated deficit	(329,811)	(308,296)
Accumulated other comprehensive income	208	172
TOTAL STOCKHOLDERS' DEFICIT	(24,777)	(17,592)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 23,041	\$ 18,131

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue	\$ 74	\$ 1	\$ 75	\$ 65
Royalty revenue	16	26	30	43
Total revenue	90	27	105	108
Operating expenses:				
Cost of revenue	36	—	36	20
Research and development	3,471	3,514	3,800	4,995
General and administrative	1,930	2,377	3,677	5,033
Total operating expenses	5,437	5,891	7,513	10,048
Loss from operations	(5,347)	(5,864)	(7,408)	(9,940)
Other income (expense), net:				
Interest income	55	62	102	143
Interest expense	(695)	(679)	(1,486)	(1,287)
Issuance costs for common stock warrant liabilities	—	—	(393)	—
Loss on initial issuance of equity	—	—	(4,582)	—
Change in fair value of common stock warrant liabilities	(4,132)	(515)	(5,192)	1,995
Change in fair value of derivative liabilities	(3,333)	(439)	(2,620)	708
Research and development tax credits and unrestricted grants	28	16	64	211
Total other income (expense), net	(8,077)	(1,555)	(14,107)	1,770
Net loss before income taxes	(13,424)	(7,419)	(21,515)	(8,170)
Income tax expense	—	—	—	—
Net loss	\$ (13,424)	\$ (7,419)	\$ (21,515)	\$ (8,170)
Other comprehensive income (loss):				
Foreign currency translation adjustments	\$ (8)	\$ 63	\$ 36	\$ 78
Total other comprehensive income (loss)	(8)	63	36	78
Comprehensive loss	\$ (13,432)	\$ (7,356)	\$ (21,479)	\$ (8,092)
Net loss per share – basic and diluted	\$ (1.08)	\$ (0.78)	\$ (1.79)	\$ (0.89)
Weighted average common shares used to compute basic and diluted net loss per share	12,382,702	9,523,592	12,015,498	9,176,063

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Deficit
	Shares	Amount				
Balances at December 31, 2025	10,849,974	\$ 1	\$ 290,531	\$ (308,296)	\$ 172	\$ (17,592)
Issuance of common stock	928,333	—	4,418	—	—	4,418
Stock-based compensation expense	—	—	1,312	—	—	1,312
Issuance of stock options as payment of bonus liability	—	—	1,103	—	—	1,103
Foreign currency translation adjustment	—	—	—	—	44	44
Net loss	—	—	—	(8,091)	—	(8,091)
Balances at March 31, 2026	11,778,307	\$ 1	\$ 297,364	\$ (316,387)	\$ 216	\$ (18,806)
Issuance of common stock	1,000,000	—	6,421	—	—	6,421
Stock-based compensation expense	—	—	1,040	—	—	1,040
Foreign currency translation adjustment	—	—	—	—	(8)	(8)
Net loss	—	—	—	(13,424)	—	(13,424)
Balances at June 30, 2026	12,778,307	\$ 1	\$ 304,825	\$ (329,811)	\$ 208	\$ (24,777)
Balances at December 31, 2024	8,089,565	1	273,194	(282,123)	71	(8,857)
Issuance of common stock	578,205	—	2,673	—	—	2,673
Stock-based compensation expense	—	—	1,947	—	—	1,947
Foreign currency translation adjustment	—	—	—	—	15	15
Net loss	—	—	—	(751)	—	(751)
Balances at March 31, 2025	8,667,770	\$ 1	\$ 277,814	\$ (282,874)	\$ 86	\$ (4,973)
Issuance of common stock	794,301	—	2,412	—	—	2,412
Stock-based compensation expense	—	—	1,367	—	—	1,367
Foreign currency translation adjustment	—	—	—	—	63	63
Net loss	—	—	—	(7,419)	—	(7,419)
Balances at June 30, 2025	9,462,071	\$ 1	\$ 281,593	\$ (290,293)	\$ 149	\$ (8,550)

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	\$ (21,515)	\$ (8,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	708	770
Non-cash lease expense	321	270
Issuance costs for common stock warrant liabilities	393	—
Loss on initial issuance of equity	4,582	—
Issuance of common stock as payment of outstanding indebtedness	—	8
Change in fair value of common stock warrant liabilities	5,192	(1,995)
Change in fair value of derivative liabilities	2,620	(708)
Stock-based compensation expense	2,352	3,314
Accretion of debt discount	525	488
Non-cash interest expense on notes payable	766	24
Changes in operating assets and liabilities:		
Accounts receivable	(43)	64
Inventory	—	(11)
Prepaid expenses and other current assets	(1,412)	(751)
Accounts payable	250	(412)
Accrued liabilities	(1,417)	(2,307)
Operating lease obligations	(438)	(339)
Net cash used in operating activities	(7,116)	(9,755)
Cash flows from investing activities:		
Purchases of property and equipment	(1)	—
Net cash used in investing activities	(1)	—
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of offering costs	11,745	4,977
Payments of notes payable	(182)	(171)
Net cash provided by financing activities	11,563	4,806
Effect of foreign exchange rate changes on cash and restricted cash	36	79
Net increase (decrease) in cash, cash equivalents and restricted cash	4,482	(4,870)
Cash, cash equivalents and restricted cash – beginning of period	5,247	12,213
Cash, cash equivalents and restricted cash – end of period	\$ 9,729	\$ 7,343
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	\$ 9,671	\$ 7,285
Restricted cash	58	58
Cash, cash equivalents and restricted cash	\$ 9,729	\$ 7,343
Supplemental disclosure of non-cash investing and financing activities:		
Common stock warrant liability recorded upon public stock offering	\$ 5,882	\$ —
Issuance of stock options as payment of bonus liability	\$ 1,103	\$ —
Issuance of common stock as payment of outstanding indebtedness	\$ —	\$ 108
Supplemental cash flow information:		
Cash paid for interest expense	\$ 195	\$ 775

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Nature of the Business

Clene Inc. (the “Company,” “we,” “us,” or similar such references) is a clinical-stage pharmaceutical company pioneering the discovery, development, and commercialization of novel clean-surfaced nanotechnology therapeutics. We have developed an electro-crystal-chemistry drug development platform that enables production of concentrated, stable, highly active, clean-surfaced nanocrystal suspensions. We have multiple drug assets currently in development for applications primarily in neurology. Our 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”). Our patented electro-crystal-chemistry manufacturing platform further enables us to develop very low concentration dietary supplements to advance the health and well-being of broad populations. These dietary supplements can vary greatly and include nanocrystals of varying composition, shapes and sizes as well as ionic solutions with diverse metallic constituents. Dietary supplements are marketed and distributed through our wholly-owned subsidiary, dOrbital, Inc., or through 4Life Research LLC (“4Life”), a related party (see Note 8 and Note 15).

Going Concern

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

We have incurred significant losses and negative cash flows from operations since our inception. We have not generated significant revenue since our inception, and we do not anticipate generating significant revenue unless we successfully complete development and obtain regulatory approval for commercialization of a drug candidate. We expect to incur additional losses in the future, particularly as we advance the development of our clinical-stage drug candidates, continue research and development of our preclinical drug candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our senior secured convertible promissory notes issued in December 2024 (the “2024 SSCP Notes”), we are required to maintain unrestricted cash and cash equivalents of at least \$2.0 million to avoid acceleration of the full balance of the 2024 SSCP Notes (see Note 8). These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

To mitigate our funding needs, we plan to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as utilizing our existing at-the-market facility and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the three and six months ended June 30, 2026, we raised \$7.0 million and \$13.0 million, respectively, of gross proceeds from registered direct offerings of equity securities (see Note 13). While we have implemented cost-saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts, reducing employee compensation, and eliminating certain staff positions, we have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date the condensed consolidated financial statements are issued.

The accompanying condensed consolidated financial statements 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, the accompanying condensed consolidated financial statements 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.

Note 2. Summary of Significant Accounting Policies***Basis of Presentation***

The accompanying condensed consolidated financial statements include the accounts of Clene Inc. and our wholly-owned subsidiaries, Clene Nanomedicine, Inc. (“Clene Nanomedicine”), a subsidiary incorporated in Delaware, Clene Australia Pty Ltd (“Clene Australia”), a subsidiary incorporated in Australia, Clene Netherlands B.V. (“Clene Netherlands”), a subsidiary incorporated in the Netherlands, and dOrbital, Inc., a subsidiary incorporated in Delaware, after elimination of all intercompany accounts and transactions. We have prepared the accompanying condensed consolidated financial statements in accordance with United States (“U.S.”) Generally Accepted Accounting Principles (“GAAP”) for interim financial reporting and as required by Regulation S-X, Rule 10-01. The condensed consolidated financial statements have been prepared on the same basis as our audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The financial data and other information disclosed in the condensed consolidated financial statements and related notes for the three and six months ended June 30, 2026 and 2025 are unaudited.

Results of operations for the three and six months ended June 30, 2026 and 2025 are not necessarily indicative of the results for the entire fiscal year or any other period. The condensed consolidated financial statements for the three and six months ended June 30, 2026 and 2025 should be read in conjunction with the audited consolidated financial statements included in our Annual Report on Form 10-K.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and disclosure of contingent assets and liabilities, and the reported amounts of expenses. We base our estimates on historical experience and various other assumptions that we believe to be reasonable. Actual results may differ from those estimates or assumptions. Estimates are periodically reviewed in light of changes in circumstances, facts, and experience, and any changes in estimates will be recorded in future periods as they develop.

Risks and Uncertainties

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on future financial condition, results of operations, or cash flows: ability to obtain additional financing; regulatory approval and market acceptance of, and reimbursement for, product candidates; performance of third-party contract research organizations (“CROs”) and clinical vendors upon which we rely; protection of our intellectual property; litigation or claims against us based on intellectual property, patent, product, regulatory, or other factors; and our ability to attract and retain employees necessary to support our growth. The product candidates we develop require approvals from regulatory agencies prior to commercial sales. There can be no assurance that our current and future product candidates will receive the necessary approvals or be commercially successful. If we are denied approval or approval is delayed, it will have a material adverse impact on our business and our condensed consolidated financial statements.

Concentrations of Credit Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash. Our cash is held in financial institutions and amounts on deposit may at times exceed federally insured limits. We have not experienced any losses on our deposits of cash and do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Cash and Cash Equivalents

We consider all short-term investments with original maturities of 90 days or less when purchased to be cash equivalents.

Restricted Cash

We classify cash as restricted when it is unavailable for withdrawal or use in our general operating activities. Restricted cash is classified as current and noncurrent on the condensed consolidated balance sheets based on the nature of the restriction. Our restricted cash balance includes contractually restricted deposits related to our corporate credit card.

Inventory

Inventory is stated at historic cost on a first-in first-out basis. Our inventory consisted of \$23,000 in raw materials and \$14,000 in finished goods as of June 30, 2026 and December 31, 2025. Inventory relates to our dietary supplement products.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Property and equipment consist of laboratory and office equipment, computer software, and leasehold improvements. Depreciation is calculated using the straight-line method over the estimated economic useful lives of the assets, which are 3 to 5 years for laboratory equipment, 3 to 7 years for furniture and fixtures, and 2 to 5 years for computer software. Leasehold improvements are amortized over the lesser of the estimated lease term or the estimated useful life of the assets. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated or amortized in accordance with the above useful lives once placed into service. Upon retirement or sale, the related cost and accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in the condensed consolidated statements of operations and comprehensive loss. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred.

We capitalize costs to obtain or develop computer software for internal use, including development costs incurred during the software development stage and costs to obtain software for access and conversion of historical data. We also capitalize costs to modify, upgrade, or enhance existing internal-use software that result in additional functionality. We expense costs incurred during the preliminary project stage, training costs, data conversion costs, and maintenance costs.

Debt

When debt is issued and a derivative is required to be separated (e.g., bifurcated conversion option) or another separate freestanding financial instrument (e.g., warrant) is issued, costs and fees incurred are allocated to the instruments issued (or bifurcated) in proportion to the allocation of proceeds. When some portions of the costs and fees relate to a bifurcated derivative or freestanding financial instrument that is being subsequently measured at fair value, those allocated costs are expensed immediately. Debt discounts, debt premiums, and debt issuance costs related to debt are recorded as deductions that net against the principal value of the debt and are amortized to interest expense over the contractual term of the debt using the effective interest method.

In accordance with ASC 470-20, *Debt with Conversion and Other Options*, when we issue debt with warrants, we treat the warrants as a debt discount, recorded as a contra-liability against the debt, and amortize the balance over the life of the underlying debt as interest expense in the condensed consolidated statements of operations and comprehensive loss. The offset to the contra-liability is recorded as additional paid-in capital in the condensed consolidated balance sheets if the warrants are not treated as a derivative or liability under ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). Otherwise, the offset to the contra-liability is recorded as a warrant liability in the condensed consolidated balance sheets and is subject to re-measurement to fair value at each balance sheet date, with any changes in fair value recognized in the condensed consolidated statements of operations and comprehensive loss. If the debt is retired early, the associated debt discount is then recognized immediately as interest expense in the condensed consolidated statements of operations and comprehensive loss.

Convertible Debt

In accordance with ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, when we issue notes with conversion features, we evaluate if the conversion feature is freestanding or embedded. If the conversion feature is embedded, we do not separate the conversion feature from the host contract for convertible notes that are not required to be accounted for as derivatives, or that do not result in substantial premiums accounted for as paid-in-capital. Consequently, we account for a convertible note as a single liability measured at its amortized cost as long as no other features require separation and recognition as derivatives. If the conversion feature is freestanding, or is embedded and meets the requirements to be separated, we account for the conversion feature as a derivative under ASC 815, *Derivatives and Hedging* ("ASC 815"). We record the derivative instrument at fair value at inception, and subsequently re-measure to fair value at each reporting period and immediately prior to the extinguishment of the derivative instrument, with any changes recorded in the condensed consolidated statements of operations and comprehensive loss.

Leases

At inception of a contract, we determine if a contract meets the definition of a lease. We determine if the contract conveys the right to control the use of an identified asset for a period of time. We assess throughout the period of use whether we have both of the following: (i) the right to obtain substantially all the economic benefits from use of the identified asset, and (ii) the right to direct the use of the identified asset. This determination is reassessed if the terms of the contract are changed. Leases are classified as operating or finance leases based on the terms of the lease agreement and certain characteristics of the identified asset. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments less any lease incentives received. At the lease commencement date, the discount rate implicit in the lease is used to discount the lease liability if readily determinable. If not readily determinable or leases do not contain an implicit rate, our incremental borrowing rate is used as the discount rate. Our policy is to not record leases with an original term of twelve months or less within the condensed consolidated balance sheets and we recognize lease expense for these short-term leases on a straight-line basis over the lease term.

Certain lease agreements may require us to pay additional amounts for taxes, insurance, maintenance, and other expenses, which are generally referred to as non-lease components. Such variable non-lease components are treated as variable lease payments and recognized in the period in which the obligation for these payments is incurred. Variable lease components and variable non-lease components are not measured as part of the right-of-use asset and liability. Only when lease components and their associated non-lease components are fixed are they accounted for as a single lease component and are recognized as part of a right-of-use asset and liability. Total contract consideration is allocated to the fixed lease and non-lease component. This policy election applies consistently to all asset classes under lease agreements.

Leases may contain clauses for renewal at our option. Payments to be made in option periods are recognized as part of the right-of-use lease assets and lease liabilities when it is reasonably certain that the option to extend the lease will be exercised, or is not at our option. We determine whether the reasonably certain threshold is met by considering contract-, asset-, market-, and entity-based factors. Operating lease expense, which is recognized on a straight-line basis over the lease term, and the amortization of finance lease right-of-use assets, which are included in property and equipment and depreciated, are included in research and development or general and administrative expenses consistent with the leased assets' primary use. Accretion on the liabilities for finance leases is included in interest expense.

Contingent Earn-Out Liabilities

We became a public company on December 30, 2020 via reverse recapitalization, pursuant to which we granted contingent earn-out awards (the "Contingent Earn-outs") in the form of shares of our common stock, par value \$0.0001 per share, to be paid to certain stockholders and former officers and directors if we had achieved market-based milestones within three to five years following the Reverse Recapitalization. In accordance with ASC 815, the Contingent Earn-outs were not indexed to our own stock and were accounted for as a liability and subsequently remeasured to fair value at each reporting date, with changes recorded as a component of other income (expense), net. As of December 31, 2025, the milestones had not been achieved and the Contingent Earn-outs were cancelled.

Common Stock Warrants

We account for common stock warrants as either equity- or liability-classified instruments based on an assessment of the warrant terms. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all the requirements for equity classification under ASC 815, including whether the warrants are indexed to our common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and, for liability-classified warrants, at each reporting period end date while the warrants are outstanding.

Grant Funding

We may submit applications to receive grant funding from governmental and non-governmental entities. We account for grants by analogizing to the grant accounting model under IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance* ("IAS 20"). We recognize grant funding without conditions or continuing performance obligations, including certain research and development tax credits, as other income in the condensed consolidated statements of operations and comprehensive loss. We accrue certain research and development tax credits receivable in other current assets (see Note 4) in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage and we recognize other income in the condensed consolidated statements of operations and comprehensive loss. After submission of our tax returns, we receive a cash refund of certain research and development tax credits and relieve the receivable.

We recognize grant funding with conditions or continuing performance obligations as a reduction in research and development or general and administrative expenses in the period during which the related qualifying expenses are incurred and as the conditions or performance obligations are fulfilled. Any amount received in advance of fulfilling such conditions or performance obligations is recorded in accrued liabilities (see Note 6) if the conditions or performance obligations are expected to be met within the next twelve months. We recognized grant funding as a reduction of research and development expenses totaling \$1.9 million and \$2.1 million during the three months ended June 30, 2026 and 2025, respectively; and \$5.9 million and \$6.2 million during the six months ended June 30, 2026 and 2025, respectively. We recognized grant funding as a reduction of general and administrative expenses totaling \$0.1 million and \$0.1 million during the three months ended June 30, 2026 and 2025, respectively; and \$0.3 million and \$0.2 million during the six months ended June 30, 2026 and 2025, respectively.

In October 2023 we were awarded a grant (“the NIH Grant”) in collaboration with New York University (“NYU”) as prime awardee (formerly Columbia University), and Synaptique, a neurology specialty health clinic, from the National Institutes of Health (“NIH”). The NIH Grant was awarded pursuant to the Accelerating Access to Critical Therapies for ALS Act to support up to a four-year Expanded Access Program (the “ACT-EAP”) for CNM-Au8® treatment of ALS. The NIH Grant totaled \$45.1 million and subawards to us may total up to \$30.9 million in aggregate and may extend to August 31, 2027. Subawards are awarded annually and subaward funds are paid to us as reimbursement for expenditures to support the ACT-EAP. Subawards for the first, second, and third year of the ACT-EAP totaled \$7.3 million, \$8.0 million, and \$8.0 million respectively. We recognized grant revenue totaling \$1.8 million and \$2.1 million during the three months ended June 30, 2026 and 2025, respectively; and \$6.1 million and \$6.4 million during the six months ended June 30, 2026 and 2025, respectively, which we recognized as reductions of research and development and general and administrative expenses.

Foreign Currency Translation and Transactions

Our functional and reporting currency is the U.S. dollar (“USD”). Clene Australia and Clene Netherlands determined their functional currencies to be the Australian dollar and Euro, respectively. The results of our foreign currency operations are translated into USD at the average exchange rates during the period, assets and liabilities are translated using the exchange rate as of the balance sheet date, and stockholders’ deficit is translated using historical rates. Adjustments from the translation of the results of our foreign currency operations are excluded from net loss and are accumulated in a separate component of stockholders’ deficit. We also incur foreign exchange transaction gains and losses for purchases denominated in foreign currencies. Foreign exchange transaction gains and losses are included in other income (expense), net, as incurred.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders’ deficit that result from transactions and economic events other than those with stockholders. The only elements of other comprehensive loss in any periods presented were the translation of foreign currency denominated balances of Clene Australia and Clene Netherlands to USD for consolidation.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated using our weighted-average outstanding common shares. Shares issuable for little or no cash consideration, such as pre-funded warrants, shall be considered outstanding common shares upon the satisfaction of any contingent conditions or when there are no contingent conditions. Diluted net loss per share attributable to common stockholders is calculated using our weighted-average outstanding common shares including the dilutive effect of securities as determined under the treasury stock method, except for the dilutive effect of convertible notes payable, which is calculated under the if-converted method, even if the embedded conversion option is out-of-the-money. In periods in which we report a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Segment Information

We report segment information based on ASC 280 *Segment Reporting* (“ASC 280”), which defines operating segments as components of a company that engage in activities from which it may recognize revenues and incur expenses, and for which operating results are regularly reviewed by the entity’s chief operating decision maker (“CODM”) to make decisions regarding resource allocation and assess performance, and for which discrete financial information is available. We determined that the Company is a single operating and reportable segment (“Products”) focused on treating central nervous system disorders through discovery, development, and commercialization of our novel CSN therapeutics. Our chief executive officer acts as the CODM and allocates resources and assesses performance at a consolidated level. Segment information is further described in Note 16.

Income Taxes

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the condensed consolidated financial statements or in our tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement basis and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. We recognize deferred tax assets to the extent we believe these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and recent results of operations. If we determine that we would be able to realize any deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

We record uncertain tax positions in accordance with ASC 740, *Income Taxes*, on the basis of a two-step process to (i) determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position, and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits within income tax expense in the condensed consolidated statements of operations and comprehensive loss. Any accrued interest and penalties related to uncertain tax positions will be reflected as liabilities in the condensed consolidated balance sheets.

Stock-Based Compensation

We account for stock-based compensation arrangements using a fair value-based method for costs related to all share-based payments. Stock-based compensation expense is recorded in research and development and general and administrative expenses based on the classification of the work performed by the grantees. The fair value is recognized over the period during which a grantee is required to provide services in exchange for the share-based payment, known as the requisite service period (usually the vesting period), on a straight-line basis. We generally grant stock options with a four-year requisite service period. We elect to account for forfeitures as they occur, rather than estimating expected forfeitures. We determine the fair value of stock option awards using a Black-Scholes option pricing model based on the closing price of our common stock on the date of grant.

Certain stock options may vest based upon performance conditions instead of service conditions, such as the achievement of regulatory milestones or financial performance measures. Compensation expense will be recognized when the conditions become probable of being satisfied. For the grant-date fair value, we estimate the expected term of stock options with performance conditions based upon the nature of the conditions. If the expected term is not estimable and the achievement of performance conditions is not probable, we use the contractual term as the expected term.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (“ASU 2024-03”). ASU 2024-03 requires that public entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. In January 2025, the FASB clarified the effective date of ASU 2024-03 with the issuance of ASU 2025-01, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date* (“ASU 2025-01”). The guidance is effective for annual periods beginning after December 15, 2026, and interim periods within annual periods beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the impact of ASU 2024-03.

In September 2025, the FASB issued ASU 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40)* (“ASU 2025-06”). ASU 2025-06 requires that entities start capitalizing software costs when funding is authorized and committed and it is probable that the project will be completed and the software will be used to perform its intended function. The guidance is effective for annual periods beginning after December 15, 2027, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the impact of ASU 2025-06.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities* (“ASU 2025-10”). ASU 2025-10 establishes authoritative guidance on how to recognize, measure, and present government grants received by business entities. The guidance is effective for annual periods beginning after December 15, 2028, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the impact of ASU 2025-10.

Note 3. Cash and Cash Equivalents

Cash and cash equivalents as of June 30, 2026 were as follows:

(in thousands)	June 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents – money market funds	\$ 6,307	\$ —	\$ —	\$ 6,307
Cash	3,364	—	—	3,364
Total cash and cash equivalents	<u>\$ 9,671</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 9,671</u>

Cash and cash equivalents as of December 31, 2025 were as follows:

(in thousands)	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents – money market funds	\$ 2,211	\$ —	\$ —	\$ 2,211
Cash	2,978	—	—	2,978
Total cash and cash equivalents	<u>\$ 5,189</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,189</u>

Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of June 30, 2026 and December 31, 2025 were as follows:

(in thousands)	June 30, 2026	December 31, 2025
Metals to be used in research and development	\$ 3,072	\$ 2,736
Grants receivable	598	—
Prepaid clinical and CRO expenses	740	—
Research and development tax credits receivable	542	590
Other	211	425
Total prepaid expenses and other current assets	<u>\$ 5,163</u>	<u>\$ 3,751</u>

Note 5. Property and Equipment, Net

Property and equipment, net, as of June 30, 2026 and December 31, 2025 were as follows:

(in thousands)	June 30, 2026	December 31, 2025
Lab equipment	\$ 3,466	\$ 3,466
Office equipment	178	178
Computer software	459	459
Leasehold improvements	9,983	9,983
Construction in progress	1,299	1,298
	15,385	15,384
Less accumulated depreciation	(10,069)	(9,361)
Total property and equipment, net	<u>\$ 5,316</u>	<u>\$ 6,023</u>

Depreciation expense recorded in research and development expense and general and administrative expense during the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
General and administrative	\$ 17	\$ 29	\$ 34	\$ 95
Research and development	336	337	674	675
Total depreciation expense	<u>\$ 353</u>	<u>\$ 366</u>	<u>\$ 708</u>	<u>\$ 770</u>

Note 6. Accrued Liabilities

Accrued liabilities as of June 30, 2026 and December 31, 2025 were as follows:

(in thousands)	June 30, 2026	December 31, 2025
Accrued compensation and benefits	\$ 2,038	\$ 3,136
Deferred grants	49	1,507
Accrued CRO and clinical fees	287	198
Other	108	161
Total accrued liabilities	<u>\$ 2,482</u>	<u>\$ 5,002</u>

Note 7. Leases

We lease laboratory and office space and certain laboratory equipment under non-cancelable operating leases. The carrying value of our right-of-use lease assets is substantially concentrated in our real estate leases, while the volume of lease agreements is primarily concentrated in equipment leases. We expect that, in the normal course of business, the existing leases will be renewed or replaced by similar leases.

We have leases for three real estate properties: (i) a laboratory and manufacturing facility lease that commenced in September 2021 with a ten-year term and an option to extend for two five-year periods, (ii) a laboratory and manufacturing facility lease that commenced in February 2022 with a seven-year term and an option to extend for two five-year periods, and (iii) our corporate office lease that commenced in April 2020 for seven years with an option to extend for five years. We did not recognize the payments to be made in the option periods as part of the right-of-use asset or lease liability because the exercise of the option is not reasonably certain.

As of June 30, 2026 and December 31, 2025, our operating lease obligations had a weighted-average discount rate of 9.6% and 9.6%, respectively, and a weighted-average remaining term of 4.2 years and 4.6 years, respectively.

Maturity Analysis of Lease Obligations

The maturity analysis of our operating lease obligations as of June 30, 2026 was as follows:

(in thousands)	Operating Leases
2026 (remainder)	\$ 534
2027	1,133
2028	1,093
2029	649
2030	623
2031	422
Thereafter	—
Total minimum lease payments	4,454
Less amount representing interest/discounting	(834)
Present value of minimum lease payments	3,620
Less lease obligations, current portion	(815)
Lease obligations, net of current portion	<u>\$ 2,805</u>

Components of Lease Cost

The components of lease costs for the three and six months ended June 30, 2026 and 2025 were as follows:

(in thousands)	Three Months Ended June 30, 2026	2025	Six Months Ended June 30, 2026	2025
Operating lease costs	256	255	\$ 510	\$ 508
Short-term lease costs	—	2	—	2
Variable lease costs	79	80	136	161
Total lease costs	<u>\$ 335</u>	<u>\$ 337</u>	<u>\$ 646</u>	<u>\$ 671</u>

Supplemental Cash Flow Information

(in thousands)	Six Months Ended June 30,	
	2026	2025
Operating cash flows from operating leases	\$ (646)	\$ (671)

Note 8. Notes Payable and Convertible Notes Payable

Our notes payable and convertible notes payable as of June 30, 2026 and December 31, 2025 were as follows:

(in thousands, except interest rates)	Stated Interest Rate	June 30, 2026	December 31, 2025
Notes payable:			
Cecil County, Maryland (commenced April 2019)	8.00%	\$ 158	\$ 154
Maryland DHCD (commenced February 2019)	8.00%	794	774
Maryland DHCD (commenced May 2022)	6.00%	554	736
Senior Secured Promissory Notes (commenced December 2024)	12.00%	3,903	3,678
Senior Secured Promissory Notes (commenced August 2025)	12.00%	694	595
		6,103	5,937
Unamortized discount and debt issuance costs		(316)	(500)
Less notes payable, current portion, net of unamortized discount and debt issuance costs		(413)	(1,696)
Notes payable, net of current portion		\$ 5,374	\$ 3,741
Convertible notes payable:			
Maryland DHCD (commenced December 2022)	6.00%	\$ 5,312	\$ 5,312
Senior Secured Convertible Promissory Notes (commenced December 2024)	12.00%	7,250	6,832
Senior Secured Convertible Promissory Notes (commenced August 2025)	12.00%	975	975
		13,537	13,119
Unamortized discount and debt issuance costs		(600)	(941)
Less convertible notes payable, current portion, net of unamortized discount and debt issuance costs		—	(2,378)
Convertible notes payable		\$ 12,937	\$ 9,800

Our interest expense on notes payable and convertible notes payable for the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Interest expense on notes payable:				
Coupon interest	\$ 152	\$ 131	\$ 302	\$ 258
Amortization of debt discount and issuance costs	78	88	184	171
Total interest expense on notes payable	230	219	486	429
Interest expense on convertible notes payable:				
Coupon interest	320	296	658	540
Amortization of debt discount and issuance costs	145	164	342	318
Total interest expense on convertible notes payable	465	460	1,000	858
Total interest expense on notes payable and convertible notes payable	\$ 695	\$ 679	\$ 1,486	\$ 1,287

Maryland Loans

In April 2019, we entered into a term loan agreement (the “2019 Cecil Loan”) with Cecil County, Maryland, for \$0.1 million bearing simple interest at an annual rate of 8.00%. The 2019 Cecil Loan matures in full on April 30, 2034, with the repayment amount equal to the greater of (i) principal plus accrued interest or (ii) an amount equal to the fair market value of 1,199 shares of our common stock (the “2019 Cecil Phantom Shares”). As of June 30, 2026 and December 31, 2025, the 2019 Cecil Loan was recorded at principal plus accrued interest as it was greater than the value of the 2019 Cecil Phantom Shares.

In February 2019, we entered into a term loan agreement (the “2019 MD Loan”) with the Department of Housing and Community Development (“DHCD”), a principal department of the State of Maryland, for \$0.5 million bearing simple interest at an annual rate of 8.00%. We are subject to covenants until maturity, including limitations on our ability to retire, repurchase, or redeem our stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends. We are not in violation of any covenants. The 2019 MD Loan matures in full on February 22, 2034, with the repayment amount equal to the greater of (i) principal plus accrued interest or (ii) an amount equal to the fair market value of 5,995 shares of our common stock (the “2019 MD Phantom Shares”). As of June 30, 2026 and December 31, 2025, the 2019 MD Loan was recorded at principal plus accrued interest as it was greater than the value of the 2019 MD Phantom Shares.

In May 2022, we entered into a term loan agreement (the “2022 MD Loan”) with DHCD for up to \$3.0 million bearing simple interest at an annual rate of 6.00% for the purchase of certain manufacturing equipment (the “Assets”). We drew a total of \$1.0 million and our ability to draw the remaining \$2.0 million expired in May 2024. The first 12 payments, commencing July 1, 2022, are deferred, followed by 18 monthly installments of interest-only based on the outstanding principal, each up to \$15,000 maximum; followed by monthly installments of principal and interest in the amount of \$33,306, payable for the lesser of 30 months or until the principal and accrued and unpaid interest is fully repaid, with a balloon payment of all remaining principal and unpaid interest due on the maturity date of July 1, 2027. As of June 30, 2026 and December 31, 2025, the balance of accrued and unpaid interest was \$50,000 and \$50,000, respectively, and is recorded as part of the carrying amount of the loan. We recorded debt issuance costs of \$31,000 as a debt discount.

In December 2022, we entered into a term loan agreement (the “2022 DHCD Loan”) with DHCD for \$5.0 million bearing simple interest at an annual rate of 6.00%. The first 12 payments, commencing January 1, 2023, are deferred, followed by 48 monthly installments of interest-only, with a balloon payment of all principal and unpaid interest due on the maturity date of January 1, 2028. As of June 30, 2026 and December 31, 2025, the balance of accrued and unpaid interest was \$0.3 million and \$0.3 million, respectively, and is recorded as part of the carrying amount of the loan. At any time after December 8, 2023, DHCD may, in its sole discretion, convert up to \$5.0 million of principal into our common stock in increments of \$1.0 million, at a price equal to the greater of: (i) 97% of the 30-day trailing volume weighted average price (“VWAP”) of our common stock; or (ii) \$80.00 per share (the “DHCD Conversion Feature”). The DHCD Conversion Feature did not meet the requirements for derivative accounting. We recorded debt issuance costs of \$0.1 million as a debt discount and the effective interest rate is 5.99%.

Senior Secured Convertible Promissory Notes

In December 2024, we entered into a note purchase agreement pursuant to which we sold the 2024 SSCP Notes in a principal amount totaling \$10.0 million and bearing interest at an annual rate of 12.00%, which we amended in August 2025 (the “First 2024 SSCPN Amendment”) and in May 2026 (the “Second 2024 SSCPN Amendment”). The 2024 SSCP Notes were sold to related parties, including: (i) Kensington Clene 2024, LLC, an entity controlled by Alison Mosca, an independent director, (ii) 4Life, and (iii) La Scala Investments, LLC. 4Life and La Scala Investments, LLC, are controlled by David Lisonbee, who is also a stockholder and board member of a subsidiary of Clene. In accordance with the 2024 SSCP Note terms, we first used the proceeds to satisfy our obligations under a previous unrelated term loan. Pursuant to the Second 2024 SSCPN Amendment, the maturity date of the 2024 SSCP Notes was extended to the earlier of (i) August 13, 2027 or (ii) upon a change in control transaction. Payments were interest-only for the first 12 months, and, pursuant to the First 2024 SSCPN Amendment, interest is capitalized monthly and added to the balance of the 2024 SSCP Notes beginning in August 2025. Pursuant to the Second 2024 SSCPN Amendment, all principal and accrued interest payments were deferred until the maturity date. We recorded debt issuance costs of \$1.5 million as a debt discount at the issuance date and an additional \$0.7 million at the date of the First 2024 SSCPN Amendment. As of June 30, 2026 and December 31, 2025, the balance of accrued and unpaid interest was \$1.2 million and \$0.5 million, respectively, and is recorded as part of the carrying amount of the 2024 SSCP Notes. The First 2024 SSCPN Amendment was accounted for as a troubled debt restructuring under ASC 470, *Debt* (“ASC 470”), with no restructuring gain required to be recognized as the future cash payments were greater than the carrying amount of the 2024 SSCP Notes. The Second 2024 SSCPN Amendment was accounted for as a debt modification under ASC 470, with a change in fair value of separated derivative instruments (discussed below) of \$1.6 million recorded as a loss in earnings.

In August 2025, we entered into a note purchase agreement pursuant to which we sold senior secured convertible promissory notes (the “2025 SSCP Notes,” and together with the 2024 SSCP Notes, the “SSCP Notes”) in a principal amount totaling \$1.5 million and bearing interest at an annual rate of 12.00%, which we amended in May 2026 (the “First 2025 SSCP Amendment”). Interest is capitalized monthly and added to the balance of the 2025 SSCP Notes. Pursuant to the First 2025 SSCP Amendment, (i) the maturity date of the 2025 SSCP Notes was extended to the earlier of (A) August 13, 2027 or (B) upon a change in control transaction, and (ii) monthly payments totaling \$150,000 per month, which were scheduled to commence in September 2026, were deferred until the maturity date. We recorded debt issuance costs of \$0.2 million as a debt discount. As of June 30, 2026 and December 31, 2025, the balance of accrued and unpaid interest was \$0.2 million and \$0.1 million, respectively, and is recorded as part of the carrying amount of the notes. The First 2025 SSCP Amendment was accounted for as a debt modification under ASC 470, with a change in fair value of separated derivative instruments (discussed below) of \$0.2 million recorded as a loss in earnings.

We are subject to covenants until maturity, including a requirement to maintain unrestricted cash and cash equivalents of at least \$2.0 million pursuant to the 2024 SSCP Notes. We are not in violation of any covenants. If certain events of default occur and are continuing, the holders of a majority of the outstanding principal balance may accelerate all obligations under the SSCP Notes, plus a penalty equal to 10% of all outstanding principal and accrued and unpaid interest (the “SSCPN Default Feature”). The SSCP Notes are collateralized by substantially all our tangible and intangible property and rights (the “Collateral”). During the continuance of an event of default, if the Collateral is sold or otherwise disposed of and the proceeds thereof are insufficient to satisfy our obligations under the SSCP Notes, we shall be liable for any deficiency, together with additional interest thereon at the rate of 10% per annum (the “SSCPN Collateral Deficiency Fee”). We account for the SSCP Collateral Deficiency Fee as a contingent liability (see Note 9).

The holders of SSCP Notes may, in their sole discretion, convert up to (i) 65% of the outstanding balance of principal and accrued interest of the 2024 SSCP Notes into the number of shares of our common stock equal to the amount to be converted divided by (A) \$5.668 for principal or (B) \$4.44 for accrued interest, and (ii) 65% of the outstanding principal balance of the 2025 SSCP Notes into the number of shares of our common stock equal to the amount to be converted divided by \$4.44 (the “SSCPN Conversion Feature”). Notwithstanding, in the event a holder declines to convert its pro rata share, the remaining holders may convert additional amounts, provided that no aggregate converted amount exceeds (i) 65% of the outstanding balance of principal and accrued interest for the 2024 SSCP Notes or (ii) \$975,000 for the 2025 SSCP Notes. In the event of a change in control or any bankruptcy, liquidation, or other restructuring process, the holders may, at their option, (i) convert up to 65% of outstanding balance of principal and accrued interest for the 2024 SSCP Notes and up to 65% of the outstanding principal for the 2025 SSCP Notes into our common stock, (ii) receive a cash payment equal to 115% of the outstanding balance of principal and accrued interest for the 2024 SSCP Notes and 115% of the outstanding principal for the 2025 SSCP Notes, or (iii) any combination thereof, prior to such monetization event, before any security or claim junior to the SSCP Notes shall receive any proceeds from such monetization event (the “SSCPN Redemption Feature,” collectively with the SSCP Conversion Feature and SSCP Default Feature, the “SSCPN Derivative Liabilities”). The SSCP Derivative Liabilities met the requirements to be separated as derivative instruments and measured at fair value (see Note 12). The issuance date fair value of the SSCP Derivative Liabilities was (i) \$1.4 million for the 2024 SSCP Notes and (ii) \$0.2 million for the 2025 SSCP Notes and was recorded as a debt discount. The effective interest rates of the 2024 SSCP Notes and 2025 SSCP Notes are 18.08% and 18.78%, respectively.

We are required to file and maintain an effective registration statement covering the resale of the shares underlying the SSCP Conversion Feature or we shall pay the holders a penalty equal to 2% of the face value of the 2024 SSCP Notes or 2025 SSCP Notes, as applicable, upon the occurrence of any such failure and for each 30-day period during which such failure is continuing (the “SSCPN Registration Fee”). The aggregate penalty will in no event exceed 10% of the face value of the 2024 SSCP Notes or the 2025 SSCP Notes, as applicable. We account for the SSCP Registration Fee as a registration payment arrangement to be evaluated as a contingent liability (see Note 9).

Debt Maturities

Future debt payments, net of unamortized discounts and debt issuance costs, without giving effect to any potential future exercise of equity conversion features, are as follows:

(in thousands)	2019 MD Loan	2019 Cecil Loan	2022 MD Loan	2022 DHCD Loan	2024 SSCP Notes	2025 SSCP Notes	Total
2026 (remainder)	\$ —	\$ —	\$ 187	\$ —	\$ —	\$ —	\$ 187
2027	—	—	317	—	10,000	1,500	11,817
2028	—	—	—	5,000	—	—	5,000
2029	—	—	—	—	—	—	—
2030	—	—	—	—	—	—	—
2031	—	—	—	—	—	—	—
Thereafter	500	100	—	—	—	—	600
Total debt principal payments	500	100	504	5,000	10,000	1,500	17,604
Accrued and unpaid interest	294	58	50	312	1,153	169	2,036
Unamortized discount and debt issuance costs	—	—	(6)	(20)	(764)	(126)	(916)
Future debt payments, net	\$ 794	\$ 158	\$ 548	\$ 5,292	\$ 10,389	\$ 1,543	\$ 18,724

Note 9. Commitments and Contingencies

Commitments

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, subject to payment of our remaining obligations under binding purchase orders and, in certain cases, nominal early termination fees. These commitments are not deemed significant.

As of June 30, 2026 and December 31, 2025, we had commitments under various agreements for capital expenditures totaling \$1.6 million and \$0.2 million, respectively, related to the construction of our manufacturing facilities.

Contingencies

From time to time, we may have certain contingent legal liabilities that arise in the ordinary course of business activities. We accrue a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. We are not aware of any current material pending legal matters or claims.

We received two grants from the National Multiple Sclerosis Society (“NMSS”): (i) \$0.3 million in September 2019 (the “2019 Grant”) for our VISIONARY-MS clinical trial, and (ii) \$0.7 million in May 2023 (the “2023 Grant”) for our REPAIR-MS clinical trial. Pursuant to the grants, if we make future commercial sales of CNM-Au8 for MS, we will repay: (i) 50% of the grants upon the first commercial sale, (ii) an additional 50% of the grants upon cumulative sales of \$10.0 million, (iii) an additional 150% of the grants upon cumulative sales of \$50.0 million, and (iv) an additional 200% of the grants upon cumulative sales of \$100.0 million, with the maximum repayment of 450% of the grants if all milestones are achieved. If NMSS has not yet received aggregate repayments equal to 300% of the 2019 Grant or 150% of the 2023 Grant, then the following events will trigger repayment of 300% of the 2019 Grant, or \$1.0 million, and 150% of the 2023 Grant, or \$1.0 million, less any amounts previously paid: (i) sale of all or substantially all our assets and business, (ii) sale of any portion of our assets and business including CNM-Au8 for MS treatment, (iii) exclusive licensing of our intellectual property claiming CNM-Au8 for MS treatment, (iv) a collaboration with a third-party to develop CNM-Au8 for MS treatment (2019 Grant only), or (v) licensing of our commercialization rights to CNM-Au8 for MS treatment (2023 Grant only). As of June 30, 2026, we have not met any of the above milestones. We account for these provisions in accordance with ASC 450, *Contingencies* (“ASC 450”). We assessed the likelihood of each event as less than probable and therefore no contingent liability is recognized. Our estimate of the possible range of loss is between the minimum and maximum repayment amounts, equal to 50% and 450% of each grant, or approximately \$0.2 million and \$1.5 million for the 2019 Grant, respectively; and approximately \$0.3 million and \$3.0 million for the 2023 Grant, respectively. However, it is at least reasonably possible that our estimate of the likelihood of each contingent event and the possible range of loss will change in the near term.

We account for the SSCPN Collateral Deficiency Fee and SSCPN Registration Fee (see Note 8) as contingent liabilities in accordance with ASC 450 that were not probable as of June 30, 2026, and therefore no contingent liabilities were recorded. Our estimate of the possible range of loss for the SSCPN Registration Fee is between \$0.2 million, which is equal to the loss upon initial failure to register the SSCPN Conversion Feature underlying shares, and \$1.2 million, which is equal to the contractually-limited maximum loss upon continued failure to register the SSCPN Conversion Feature underlying shares. We are not able to estimate a possible range of loss for the SSCPN Collateral Deficiency Fee. It is at least reasonably possible that our estimate of the likelihood of each contingent event and the possible range of loss will change in the near term.

Note 10. Income Taxes

The components of loss before income taxes for the three and six months ended June 30, 2026 and 2025 were as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
United States	\$ (13,377)	\$ (7,381)	\$ (21,483)	\$ (8,082)
Foreign	(47)	(38)	(32)	(88)
Net loss before income taxes	<u>\$ (13,424)</u>	<u>\$ (7,419)</u>	<u>\$ (21,515)</u>	<u>\$ (8,170)</u>

We are subject to taxation in the U.S., Australia, Netherlands, and various state jurisdictions. Our tax returns from 2016 to present are subject to examination by U.S. and state authorities due to the carry forward of unutilized net operating losses and research and development credits. We currently have no pending examinations. We compute our quarterly income tax provision by using a forecasted annual effective tax rate and adjust for any discrete items arising during the quarter. The primary difference between the effective tax rate and the federal statutory tax rate relates to the full valuation allowance on our net operating losses and other deferred tax assets.

Note 11. Benefit Plans

401(k) Plan

Our 401(k) plan is a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. We match 100% of a participating employee's deferral contributions up to 3% of annual compensation, limited to \$4,500 of matching contributions. Our contributions to the 401(k) plan totaled \$52,000 and \$48,000 during the three months ended June 30, 2026 and 2025, respectively; and \$0.1 million and \$0.1 million during the six months ended June 30, 2026 and 2025, respectively.

Stock Compensation Plans

The Clene Nanomedicine, Inc. 2014 Stock Plan (the "2014 Plan") was adopted in July 2014. Effective as of the closing of the Reverse Recapitalization, no additional awards may be granted under the 2014 Plan. As of June 30, 2026, a total of 109,060 stock options remained outstanding under the 2014 Plan.

The Clene Inc. 2020 Amended Stock Plan (the "2020 Plan") was adopted in December 2020 and amended in May 2023, May 2024, May 2025, and May 2026. Currently, 4,220,000 shares of our common stock are reserved for issuance thereunder. As of June 30, 2026, a total of 3,366,236 stock options and other stock awards had been granted under the 2020 Plan, and 853,764 shares remained available for future grant.

Stock-Based Compensation Expense

Stock-based compensation expense recorded in research and development expense and general and administrative expense during the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026(1)	2025
General and administrative	\$ 514	\$ 767	\$ 1,112	\$ 1,768
Research and development	526	600	1,240	1,546
Total stock-based compensation expense	<u>\$ 1,040</u>	<u>\$ 1,367</u>	<u>\$ 2,352</u>	<u>\$ 3,314</u>

(1) Excludes \$1.1 million of stock options issued to pay deferred employee compensation recorded in accrued liabilities.

Stock-based compensation expense by award type during the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026(1)	2025
Stock options	\$ 1,040	\$ 1,496	\$ 2,352	\$ 3,443
Stock awards(2)	—	(129)	—	(129)
Total stock-based compensation expense	\$ 1,040	\$ 1,367	\$ 2,352	\$ 3,314

(1) Excludes \$1.1 million of stock options issued to pay deferred employee compensation recorded in accrued liabilities.

(2) Stock awards include rights to restricted stock awards with market-based vesting conditions.

Stock Options

Outstanding stock options and related activity during the six months ended June 30, 2026 was as follows:

(in thousands, except share, per share, and term data)	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Term (Years)	Intrinsic Value
Outstanding – December 31, 2025	2,787,201	\$ 20.79	8.11	\$ 1,013
Granted	674,027	5.51	9.77	—
Forfeited	(1,413)	6.84	—	—
Expired	(858)	52.73	—	—
Outstanding – June 30, 2026	3,458,957	\$ 17.81	8.03	\$ 1,746
Vested and exercisable – June 30, 2026	2,235,242	\$ 23.67	7.72	\$ 1,162
Vested, exercisable or expected to vest – June 30, 2026	3,458,957	\$ 17.81	8.03	\$ 1,746

As of June 30, 2026 and December 31, 2025, we had approximately \$4.3 million and \$4.8 million, respectively, of unrecognized stock-based compensation costs related to unvested stock options that is expected to be recognized over a weighted-average period of 1.98 years and 1.52 years, respectively. Our unrecognized stock-based compensation cost excludes \$2.8 million of stock options that vest based on performance conditions that we assessed as less than probable as of June 30, 2026 and December 31, 2025.

The weighted-average grant-date fair value of stock options granted during the six months ended June 30, 2026 and 2025 was \$4.36 and \$3.28, respectively. The assumptions used to calculate the fair value of stock options granted during the six months ended June 30, 2026 and 2025 were as follows:

	Six Months Ended June 30,	
	2026	2025
Expected stock price volatility	96.64% – 107.55%	103.78% – 110.25%
Risk-free interest rate	3.65% – 4.27%	4.05% – 4.24%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 – 6.09	5.00 – 6.25

Note 12. Fair Value

Cash and cash equivalents are carried at fair value. Financial instruments, including accounts receivable, accounts payable, and accrued expenses are carried at cost, which approximates fair value given their short-term nature. Our remaining fair value measures are discussed below.

Financial Instruments with Fair Value Measurements on a Recurring Basis

The fair value hierarchy for financial instruments measured at fair value on a recurring basis as of June 30, 2026 was as follows:

(in thousands)	June 30, 2026			
	Level 1	Level 2	Level 3	Total
Cash equivalents – money market funds	\$ 6,307	\$ —	\$ —	\$ 6,307
Common stock warrant liabilities	—	—	16,137	16,137
Derivative liabilities	—	—	5,713	5,713

The fair value hierarchy for financial instruments measured at fair value on a recurring basis as of December 31, 2025 was as follows:

(in thousands)	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents – money market funds	\$ 2,211	\$ —	\$ —	\$ 2,211
Common stock warrant liabilities	—	—	5,063	5,063
Derivative liabilities	—	—	3,093	3,093

There were no transfers between Level 1, Level 2, or Level 3 during any of the periods above.

Changes in the fair value of our Level 3 financial instruments during the six months ended June 30, 2026 were as follows:

(in thousands)	Common Stock Warrant Liabilities	Derivative Liabilities
Balance – December 31, 2025	\$ 5,063	\$ 3,093
Initial fair value of instruments issued	5,882	—
Change in fair value	5,192	2,620
Balance – June 30, 2026	<u>\$ 16,137</u>	<u>\$ 5,713</u>

Changes in the fair value of our Level 3 financial instruments during the six months ended June 30, 2025 were as follows:

(in thousands)	Common Stock Warrant Liabilities	Derivative Liabilities
Balance – December 31, 2024	\$ 4,541	\$ 1,804
Change in fair value	(1,995)	(708)
Balance – June 30, 2025	<u>\$ 2,546</u>	<u>\$ 1,096</u>

Valuation of Notes Payable and Convertible Notes Payable

Our notes payable and convertible notes payable are categorized within Level 3 of the fair value hierarchy. The 2019 MD Loan and 2019 Cecil Loan are carried at the greater of principal plus accrued interest or the value of certain “phantom shares” (see Note 8) which approximates fair value. The 2022 MD Loan, 2022 DHCD Loan, and 2025 SSCP Notes are carried at amortized cost, which approximates fair value due to our credit risk and market interest rates.

The 2024 SSCP Notes are carried at their amortized cost of \$10.4 million and \$9.3 million as of June 30, 2026 and December 31, 2025, respectively. As of June 30, 2026 and December 31, 2025, amortized cost did not approximate fair value and the fair value of the 2024 SSCP Notes, excluding the SSCPN Derivative Liabilities pertaining to the 2024 SSCP Notes, was approximately \$10.1 million and \$8.2 million, respectively.

The SSCPN Derivative Liabilities met the requirements to be separated from the SSCP Notes as derivative instruments measured at fair value. We estimate the fair value of the SSCP Notes with and without the SSCPN Derivative Liabilities and calculate the difference as the implied fair value of the SSCPN Derivative Liabilities. The valuation model consists of a discounted cash flow model and a Black-Scholes option-pricing model with probability weights for the occurrence of (i) a change of control transaction, (ii) default of the Company, or (iii) held to maturity. These estimates require significant judgment. The carrying amount may fluctuate significantly and the actual settlement amount may be materially different from the estimated fair value. The unobservable valuation inputs were as follows:

	June 30, 2026	May 18, 2026 ⁽¹⁾	May 18, 2026 ⁽²⁾	May 11, 2026 ⁽³⁾	May 11, 2026 ⁽⁴⁾	December 31, 2025
Expected stock price volatility	114.20%	113.30%	120.50%	112.60%	120.40%	107.30%
Discount rate	20.00%	20.00%	20.00%	20.00%	20.00%	19.00%
Risk-free interest rate	4.00%	3.90%	3.70% – 3.80%	3.80%	3.70% – 3.80%	3.50% – 3.60%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Expected term (in years)	0.21 – 1.12	0.41 – 1.24	0.32 – 0.74	0.43 – 1.26	0.34 – 0.76	0.38 – 1.12
Probability of change of control	30.00%	30.00%	5.00%	30.00%	5.00%	20.00%
Probability of default	5.00%	5.00%	5.00%	5.00%	5.00%	35.00%
Probability of held to maturity	65.00%	65.00%	90.00%	65.00%	90.00%	45.00%

- (1) Represents the unobservable inputs to the valuation of the SSCPN Derivative Liabilities related to the 2025 SSCP Notes immediately following the First 2025 SSCPN Amendment.
- (2) Represents the unobservable inputs to the valuation of the SSCPN Derivative Liabilities related to the 2025 SSCP Notes immediately preceding the First 2025 SSCPN Amendment.
- (3) Represents the unobservable inputs to the valuation of the SSCPN Derivative Liabilities related to the 2024 SSCP Notes immediately following the Second 2024 SSCPN Amendment.
- (4) Represents the unobservable inputs to the valuation of the SSCPN Derivative Liabilities related to the 2024 SSCP Notes immediately preceding the Second 2024 SSCPN Amendment.

Valuation of the Common Stock Warrant Liabilities

Pursuant to a loan with Avenue Venture Opportunities Fund, L.P. (“Avenue”), which we repaid in 2024, we issued a warrant to purchase 150,000 shares of our common stock at \$4.6014 per share (the “2023 Avenue Warrant”). The 2023 Avenue Warrant, as amended, is classified as a liability and carried at fair value. We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of (i) settlement of the instrument upon a change of control transaction, (ii) dissolution of the Company, or (iii) held to expiration. These estimates require significant judgment. The carrying amount may fluctuate significantly and the actual settlement amount may be materially different from the estimated fair value. The unobservable valuation inputs were as follows:

	June 30, 2026	December 31, 2025
Expected stock price volatility	107.00% – 115.40%	104.40% – 119.00%
Risk-free interest rate	4.00% – 4.10%	3.50% – 3.60%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	1.09 – 2.00	0.50 – 2.50
Probability of change of control	30.00%	20.00%
Probability of dissolution	30.00%	35.00%
Probability of held to expiration	40.00%	45.00%

Pursuant to an underwritten public offering in June 2023, we issued warrants to purchase 2,500,000 shares of our common stock at \$22.00 per share (the “Tranche A Warrants”). The Tranche A Warrants expired unexercised in June 2026. The Tranche A Warrants were classified as a liability and carried at fair value. We estimated the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of (i) acceptance of a new drug application (“NDA”) by the U.S. Food and Drug Administration (“FDA”) for CNM-Au8, (ii) settlement upon a fundamental transaction, (iii) dissolution of the Company, and (iv) held to expiration. These estimates required significant judgment. The unobservable valuation inputs were as follows:

	December 31, 2025
Expected stock price volatility	124.00%
Risk-free interest rate	3.60%
Expected dividend yield	0.00%
Expected term (in years)	0.46
Probability of NDA acceptance before warrant expiration	0.00%
Probability of fundamental transaction before warrant expiration	0.00%
Probability of dissolution before warrant expiration	35.00%
Probability of held to expiration	65.00%

Pursuant to a registered direct public offering in October 2024, we issued warrants to purchase 1,546,914 shares of our common stock at \$4.82 per share (the “2024 Common Warrants”). The 2024 Common Warrants are classified as a liability and carried at fair value. We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of (i) dissolution of the Company and (ii) held to maturity. These estimates require significant judgment. The carrying amount may fluctuate significantly and the actual settlement amount may be materially different from the estimated fair value. The unobservable valuation inputs were as follows:

	June 30, 2026	December 31, 2025
Expected stock price volatility	100.90%	104.30%
Risk-free interest rate	4.20%	3.60%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	3.25	3.75
Probability of dissolution	30.00%	35.00%
Probability of held to expiration	70.00%	65.00%

Pursuant to a registered direct public offering in January 2026, we issued warrants to purchase 1,114,000 shares of our common stock at \$6.00 per share (the “Series A Warrants”). The exercise price of the Series A Warrants will increase to \$7.00 per share if (i) the Series A Warrant is exercised prior to our public announcement of the FDA’s posted action date under the Prescription Drug User Fee Act for our NDA for CNM-Au8 (the “Series A Trigger Announcement”), or (ii) the VWAP of our common stock equals or exceeds \$10.00 on the Series A Price Measurement Date, as defined below. The “Series A Price Measurement Date” means (A) the trading day on which the Series A Trigger Announcement is made, if such announcement is made prior to 9:00 a.m. (New York City time) on such trading day, or (B) the first trading day immediately following the day on which the Series A Trigger Announcement is made, if such announcement is made at or after 9:01 a.m. (New York City time) on a trading day or on a day that is not a trading day.

The Series A Warrants are classified as a liability and carried at fair value. We estimate the fair value using a Monte Carlo simulation with estimates for (i) the probability of the Series A Trigger Announcement (ii) the expected stock price increase if the Series A Trigger Announcement occurs, and (iii) the expected stock price decrease if the Series A Trigger Announcement does not occur. These estimates require significant judgment. The carrying amount may fluctuate significantly and the actual settlement amount may be materially different from the estimated fair value. The unobservable valuation inputs were as follows:

	June 30, 2026	January 13, 2026
Expected stock price volatility	102.60%	107.30%
Risk-free interest rate	4.10%	3.68%
Expected term (in years)	0.42 – 2.54	0.46 – 3.00
Probability of Series A Trigger Announcement	50.00%	35.00%
Expected stock price increase if Series A Trigger Announcement occurs	35.00%	35.00%
Expected stock price decrease if Series A Trigger Announcement does not occur	85.00%	85.00%

Pursuant to a registered direct public offering in January 2026, we issued warrants to purchase 2,599,333 shares of our common stock at \$6.00 per share (the “Series B Warrants”). The exercise price of the Series B Warrants will increase to (i) \$10.00 per share if the VWAP of our common stock equals or exceeds \$20.00 on the Series B Price Measurement Date, or (ii) \$12.50 per share if (A) the VWAP of our common stock equals or exceeds \$25.00 on the Series B Price Measurement Date, or (B) the Series B Warrant is exercised prior to our public announcement of receipt of written approval from the FDA of our NDA for CNM-Au8 in ALS, which announcement shall be made promptly after receipt of such approval (the “Series B Trigger Announcement”). The “Series B Price Measurement Date” means (A) the trading day on which the Series B Trigger Announcement is made, if such announcement is made prior to 9:00 a.m. (New York City time) on such trading day, or (B) the first trading day immediately following the day on which the Series B Trigger Announcement is made, if such announcement is made at or after 9:01 a.m. (New York City time) on a trading day or on a day that is not a trading day.

The Series B Warrants are classified as a liability and carried at fair value. We estimate the fair value using a Monte Carlo simulation with estimates for (i) the probability of the Series B Announcement (ii) the expected stock price increase if the Series B Trigger Announcement occurs, and (iii) the expected stock price decrease if the Series B Trigger Announcement does not occur. These estimates require significant judgment. The carrying amount may fluctuate significantly and the actual settlement amount may be materially different from the estimated fair value. The unobservable valuation inputs were as follows:

	June 30, 2026	January 13, 2026
Expected stock price volatility	102.60%	107.30%
Risk-free interest rate	4.10%	3.68%
Expected term (in years)	0.92 – 4.54	0.96 – 5.00
Probability of Series B Trigger Announcement	35.00%	24.00%
Expected stock price increase if Series B Trigger Announcement occurs	100.00%	100.00%
Expected stock price decrease if Series B Trigger Announcement does not occur	95.00%	95.00%

Note 13. Capital Stock

As of June 30, 2026 and December 31, 2025, our amended and restated certificate of incorporation authorized us to issue 600,000,000 shares of common stock, par value \$0.0001 per share; and 1,000,000 shares of preferred stock, par value \$0.0001 per share. As of June 30, 2026 and December 31, 2025, we had 12,778,307 and 10,849,974 shares of common stock issued and outstanding, respectively, and no shares of preferred stock issued or outstanding.

Our common stockholders are entitled to one vote per share and to notice of any stockholders’ meeting. Voting, dividend, and liquidation rights of the holders of our common stock are subject to the prior rights of holders of all classes of stock and are qualified by the rights, powers, preferences, and privileges of the holders of our preferred stock. No distributions shall be made with respect to our common stock until all declared dividends to our preferred stock have been paid or set aside for payment. Common stock is not redeemable at the option of the holder.

Common Stock Warrants

We have issued the following outstanding warrants to purchase shares of our common stock:

Warrant Class	Exercise Price	Expiration	Classification	Number of Shares Issuable	
				June 30, 2026	December 31, 2025
2023 Avenue Warrant ⁽¹⁾	\$ 4.6014	June 2028	Liability	150,000	150,000
Tranche A Warrants ⁽²⁾	\$ 22.00	June 2026	Liability	—	2,500,000
Tranche B Warrants ⁽³⁾	\$ 30.00	June 2030	Equity	2,500,000	2,500,000
2024 Common Warrants ⁽⁴⁾	\$ 4.82	October 2029	Liability	1,546,914	1,546,914
Series A Warrants ⁽⁵⁾	\$ 6.00	January 2029	Liability	1,114,000	—
Series B Warrants ⁽⁶⁾	\$ 6.00	January 2031	Liability	2,599,333	—
Total shares				7,910,247	6,696,914

(1) We issued the 2023 Avenue Warrant pursuant to a loan with Avenue (see Note 12). As of June 30, 2026 and December 31, 2025, the 2023 Avenue Warrant had not been exercised.

(2) We issued the Tranche A Warrants in a June 2023 public equity offering. Each Tranche A Warrant was exercisable for one share of our common stock. The Tranche A Warrants expired unexercised on June 16, 2026.

- (3) We issued warrants in a June 2023 public equity offering (the “Tranche B Warrants”). Each Tranche B Warrant is exercisable for one share of our common stock. The Tranche B Warrants expire on the earlier of (i) 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. As of June 30, 2026 and December 31, 2025, no Tranche B Warrants had been exercised.
- (4) We issued the 2024 Common Warrants in an October 2024 public equity offering. Each 2024 Common Warrant is exercisable for one share of our common stock. As of June 30, 2026 and December 31, 2025, no 2024 Common Warrants had been exercised.
- (5) We issued the Series A Warrants in a January 2026 public equity offering. Each Series A Warrant is exercisable for 1.2 shares of our common stock. The Series A Warrants expire three years from issuance unless, if on or after the first trading day immediately following the Series A Price Measurement Date, the closing price of our common stock is in-the-money, then we shall have the right, for a period of seven business days (such seventh day, the “Call Date”) following such trading date, to redeem or call for cancellation all or any portion of the Series A Warrants for which a notice of exercise has not yet been delivered for consideration equal to \$0.01 per share (the “Redemption Price”). Any portion not exercised by 5:00 p.m. Eastern Time on the Call Date shall be automatically redeemed by us for the Redemption Price and shall thereafter be null and void. As of June 30, 2026, no Series A Warrants had been exercised.
- (6) We issued the Series B Warrants in a January 2026 public equity offering. Each Series B Warrant is exercisable for 2.8 shares of our common stock. The Series B Warrants expire five years from issuance unless, if on or after the first trading day immediately following the Series B Price Measurement Date, the closing price of our common stock is in-the-money, then we shall have the right, for a period of seven business days following such trading date, to redeem or call for cancellation all or any portion of the Series B Warrants for which a notice of exercise has not yet been delivered for the Redemption Price. Any portion not exercised by 5:00 p.m. Eastern Time on the Call Date shall be automatically redeemed by us for the Redemption Price and shall thereafter be null and void. As of June 30, 2026, no Series B Warrants had been exercised.

Public Offerings

In October 2024, pursuant to a placement agency agreement with Canaccord Genuity LLC (“Canaccord”), we sold 725,000 shares of our common stock and pre-funded warrants to purchase up to 17,626 shares of our common stock (the “2024 Pre-Funded Warrants”). The aggregate gross proceeds were approximately \$3.5 million, excluding the proceeds, if any, from the exercise of the pre-funded warrants and before deducting placement agent fees and expenses and other expenses payable by us. We paid Canaccord a placement agent fee of 6.00% of the aggregate gross proceeds of the offering. The offering was made pursuant to our registration statement on Form S-3 (file number 333-264299), declared effective on April 26, 2022 (the “2022 S-3”), and a related prospectus supplement. Additionally, in separate, concurrent private placements, we also sold 379,930 shares of our common stock, 2024 Pre-Funded Warrants to purchase up to 424,358 shares of our common stock, and 2024 Common Warrants to purchase up to 1,546,914 shares of our common stock. The aggregate gross proceeds from the private placements was approximately \$3.8 million, of which \$1.3 million was contributed by certain of our directors, executive officers and their affiliated entities, and excludes the proceeds, if any, from the exercise of the 2024 Pre-Funded Warrants and 2024 Common Warrants. The 2024 Pre-Funded Warrants were exercisable immediately at a price of \$0.001 per share and expired when exercised in full. The 2024 Common Warrants were exercisable immediately at a price of \$4.82 per share and expire five years from issuance. The total fair value of the common stock, 2024 Pre-Funded Warrants, and 2024 Common Warrants sold in the offerings exceeded the offering proceeds by \$2.1 million, therefore pursuant to ASC 815, we recognized this amount as a loss on the initial issuance of equity during the year ended December 31, 2024. The placement agent fees and offering expenses were allocated to the common stock, 2024 Pre-Funded Warrants, and 2024 Common Warrants sold in the offering based on their relative fair values, with the amount allocated to the liability-classified 2024 Common Warrants recorded as an expense and the amounts allocated to the common stock and 2024 Pre-Funded Warrants as a reduction to their initial carrying values.

In January 2026, pursuant to a placement agency agreement with BTIG, LLC (“BTIG”), we sold 928,333 shares of our common stock, Series A Warrants to purchase up to 1,114,000 shares of our common stock, and Series B Warrants to purchase up to 2,599,333 shares of our common stock. The aggregate gross proceeds were approximately \$6.0 million, of which \$0.3 million was contributed by certain of our directors and their affiliated entities, excluding the proceeds, if any, from the exercise of the Series A Warrants and Series B Warrants and before deducting placement agent fees and expenses and other expenses payable by us. We paid BTIG a placement agent fee of 6.00% of the aggregate gross proceeds of the offering. The offering was made pursuant to our registration statement on Form S-3 (file number 333-286058), declared effective on April 25, 2025 (the “2025 S-3”), and a related prospectus supplement. The total fair value of the common stock, Series A Warrants, and Series B Warrants sold in the offerings exceeded the offering proceeds by \$4.6 million, therefore pursuant to ASC 815, we recognized this amount as a loss on the initial issuance of equity during the six months ended June 30, 2026. The placement agent fees and offering expenses were allocated to the common stock, Series A Warrants, and Series B Warrants sold in the offering based on their relative fair values, with the amounts allocated to the liability-classified Series A Warrants and Series B Warrants recorded as an expense and the amounts allocated to the common stock as a reduction to its initial carrying value.

In May 2026, pursuant to an underwriting agreement with Canaccord, we sold 1,000,000 shares of our common stock at an offering price of \$7.00 per share. The aggregate gross proceeds were \$7.0 million. We paid underwriting discounts and commissions of \$0.5 million and other offering expenses of \$0.1 million. The offering was made pursuant to our 2025 S-3 and a prospectus supplement related to the offering.

Common Stock Sales Agreement

In April 2022, we entered into an equity distribution agreement (the “2022 ATM Agreement”), which we amended in December 2022. In April 2025, we entered into an equity distribution agreement (the “2025 ATM Agreement,” and collectively with the 2022 ATM Agreement, the “ATM Agreements”). Canaccord acts as placement agent under the ATM Agreements and we may offer and sell shares of our common stock from time to time through Canaccord. The issuance and sale of common stock by us under the 2022 ATM Agreement was made pursuant to our 2022 S-3, which expired on April 26, 2025. The issuance and sale of common stock by us under the 2025 ATM Agreement was made pursuant to our 2025 S-3 and a related prospectus supplement.

Pursuant to the ATM Agreements, Canaccord is not required to sell any specific number or dollar amount of our common stock but will act as our placement agent to sell, on our behalf, all of the common stock requested by us to be sold, consistent with Canaccord’s normal trading and sales practices, on terms mutually agreed between Canaccord and us, for a fixed commission from each sale of common stock, if any. We did not effect any sales during the three and six months ended June 30, 2026. During the three and six months ended June 30, 2025, we sold 758,990 and 1,337,195 shares of our common stock, respectively, generated gross proceeds of \$2.3 million and \$5.1 million, respectively, and paid commissions of \$35,000 and \$0.1 million, respectively.

Note 14. Net Loss Per Share

The computation of basic and diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Numerator:				
Net loss attributable to common stockholders	\$ (13,424)	\$ (7,419)	\$ (21,515)	\$ (8,170)
Denominator:				
Weighted average common shares outstanding	12,382,702	9,523,592	12,015,498	9,176,063
Net loss per share attributable to common stockholders – basic and diluted	\$ (1.08)	\$ (0.78)	\$ (1.79)	\$ (0.89)

The following shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2026 and 2025 because they were antidilutive, out-of-the-money, or the issuance of such shares is contingent upon certain conditions that were not satisfied by the end of the period:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Convertible notes payable (see Note 8)	1,597,714	1,209,289	1,597,714	1,209,289
Common stock warrants (see Note 13)	7,910,247	6,818,518	7,910,247	6,818,518
Options to purchase common stock (see Note 11)	3,458,957	2,312,795	3,458,957	2,312,795
Unvested restricted stock awards (see Note 11)	—	36,778	—	36,778
Contingent earn-out shares (see Note 2)	—	329,628	—	329,628
Total shares excluded from diluted net loss per share	12,966,918	10,707,008	12,966,918	10,707,008

Note 15. Related Party Transactions

Supply and License Agreements

In August 2018, we entered into a supply agreement (the “Supply Agreement”) and license agreement (the “License Agreement”) with 4Life, an international supplier of health supplements, stockholder, and debt holder, in conjunction with 4Life’s investment in the Series C preferred stock and warrants of our predecessor. 4Life is controlled by David Lisonbee, who is also a stockholder, debt holder, and board member of a subsidiary of Clene. On April 25, 2024, we entered into an amendment to the Supply Agreement and License Agreement (the “Amended 4Life Agreements”). The Amended 4Life Agreements contain the following terms:

- **Supply Agreement.** We granted 4Life, or its affiliates and mutually-agreed upon manufacturing vendors (the “Buyer Purchasing Parties”) an exclusive right to purchase certain of our dietary supplement and non-pharmaceutical products (the “Licensed Products”), and agreed we shall exclusively sell the Licensed Products to the Buyer Purchasing Parties. The purchase price of Licensed Products shall be equal to our cost plus 20%. 4Life must sell certain amounts of Licensed Products for the calendar years beginning in 2024 and extending through 2033 (the “Minimum Sales Commitment”), with Minimum Sales Commitments for years subsequent to 2033, if applicable, to be negotiated between the Company and 4Life. Effective April 30, 2026, we permanently converted 4Life’s exclusive rights to purchase Licensed Products to non-exclusive rights based on (i) 4Life’s failure to achieve the Minimum Sales Commitment for two consecutive years, and (ii) 4Life’s failure to pay additional royalty fees to maintain exclusivity (the “Exclusivity Provision”).
- **License Agreement.** We granted 4Life an exclusive, royalty-bearing license to use, sell, and commercialize the Licensed Products. On a quarterly basis, 4Life shall pay us a royalty rate of 3% of incremental sales of Licensed Products, which is equal to the lesser of (a) the increase in net sales for the quarter over a base period quarter as determined in the License Agreement, or (b) net sales. Effective April 30, 2026, we permanently converted 4Life’s exclusive rights to use, sell, and commercialize the Licensed Products to non-exclusive rights as it failed to meet the Exclusivity Provision and did not pay us the difference between (a) the royalty fee that would otherwise have been earned by us if 4Life had met the Minimum Sales Commitment and (b) actual royalties paid to us. The term of the License Agreement will continue until December 31, 2033, unless earlier terminated pursuant to the License Agreement or Supply Agreement. The Amended 4Life Agreements are renewable for additional five-year terms upon mutual agreement of the parties.

We currently provide (i) an aqueous zinc-silver ion dietary (mineral) supplement on a non-exclusive basis to 4Life that is sold under the trade name Zinc Factor™, and (ii) an aqueous gold dietary (mineral) supplement of very low-concentration gold nanoparticles on an exclusive basis to 4Life that is sold under the trade name Gold Factor™ and is subject to royalties. Total revenue under the Amended 4Life Agreements during the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Product revenue from related parties	\$ 74	\$ —	\$ 74	\$ 63
Royalty revenue from related parties	16	26	30	43
Total revenue from related parties	<u>\$ 90</u>	<u>\$ 26</u>	<u>\$ 104</u>	<u>\$ 106</u>

Note 16. Geographic and Segment Information

Geographic Information

All our long-lived assets, composed of property and equipment, net by location, were held in the U.S. All our revenue from external customers was generated in the U.S.

Segment Information

Our Products segment measures of profit and loss is consolidated loss from operations, and its measure of total assets is consolidated total assets. Our CODM uses loss from operations predominantly in the annual budget and forecasting process to monitor variances in budget versus actual results along with consolidated total assets to determine resource allocation. Segment revenue from external customers, significant segment non-cash items, and other significant segment expense categories included within the measure of profit and loss and provided to our CODM were all based on their consolidated amounts. During the three and six months ended June 30, 2026 and 2025, these items were as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Segment revenue from external customers	\$ 90	\$ 27	\$ 105	\$ 108
Segment operating expenses:				
Cost of revenue	36	—	36	20
Research and development:				
CNM-Au8:				
Amyotrophic lateral sclerosis	712	1,468	1,536	2,811
Multiple sclerosis	37	164	107	189
Regulatory activities	371	130	567	260
General/preclinical/nonclinical	101	19	121	82
Facilities	393	386	784	805
Depreciation	336	337	674	675
Manufacturing	522	187	155	270
Research	1	2	10	7
Equipment	24	14	84	28
Maintenance	32	32	49	64
Information technology	76	54	143	119
Personnel	2,188	2,100	4,211	4,260
Stock-based compensation	526	600	1,240	1,546
Grant revenue as a reduction of research and development expense	(1,864)	(2,058)	(5,914)	(6,225)
Other segment items – Research and development(1)	16	79	33	104
General and administrative:				
Insurance	177	181	328	362
Legal	144	175	195	323
Finance and accounting	155	220	488	530
Public and investor relations	109	119	202	230
Facilities	30	31	63	61
Depreciation	17	29	34	95
Information technology	40	47	62	96
Personnel	779	788	1,417	1,620
Stock-based compensation	514	767	1,112	1,768
Grant revenue as a reduction of general and administrative expense	(93)	(65)	(329)	(228)
Other segment items – General and administrative(2)	58	85	105	176
Segment loss from operations	(5,347)	(5,864)	(7,408)	(9,940)
Reconciliation of segment loss from operations:				
Adjustments and reconciling items	—	—	—	—
Consolidated loss from operations	\$ (5,347)	\$ (5,864)	\$ (7,408)	\$ (9,940)

(1) Includes expenses for travel, meals, dues, subscriptions, continuing education, and other miscellaneous expenses.

(2) Includes expenses for travel, meals, dues, subscriptions, continuing education, lobbying, banking fees, postage, and other office and miscellaneous expenses.

Our revenue during the three and six months ended June 30, 2026 and 2025 was predominantly with a single customer, 4Life, through our Amended 4Life Agreements (see Note 15). A reconciliation of the total of the Products segment loss from operations to consolidated net loss before income taxes for the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Segment loss from operations	\$ (5,347)	\$ (5,864)	\$ (7,408)	\$ (9,940)
Total other income (expense), net ⁽¹⁾	(8,077)	(1,555)	(14,107)	1,770
Net loss before income taxes	<u>\$ (13,424)</u>	<u>\$ (7,419)</u>	<u>\$ (21,515)</u>	<u>\$ (8,170)</u>

(1) Represents consolidated total other income (expense), net, as reported on the consolidated statements of operations and comprehensive loss.

Products segment assets exclude corporate assets, such as cash, restricted cash, and corporate facilities. Total assets as of June 30, 2026 and December 31, 2025 were as follows:

(in thousands)	June 30, 2026	December 31, 2025
Total assets:		
Products	\$ 13,290	\$ 12,828
Corporate	9,751	5,303
Consolidated	<u>\$ 23,041</u>	<u>\$ 18,131</u>

Additions to long-lived assets during the six months ended June 30, 2026 were insignificant. We had no additions during the six months ended June 30, 2025.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. Unless the context otherwise requires, for purposes of this section, the terms the “Company,” “we,” “us,” or “our” are intended to mean the business and operations of Clene Inc. and its consolidated subsidiaries.

Business 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, materials science, and biochemistry. Our platform process results in nanocrystals with faceted structures and surfaces that are free of the chemical surface modifications that accompany other production methods. Many traditional methods of nanoparticle synthesis involve the unavoidable deposition of potentially toxic organic residues and stabilizing surfactants on the particle surfaces. Synthesizing stable nanocrystals that are both nontoxic and highly catalytic has overcome this significant hurdle in harnessing transition metal catalytic activity for therapeutic use. Our clean-surfaced nanocrystals exhibit catalytic activities many-fold higher than other commercially available nanoparticles, produced using various techniques, that we have comparatively evaluated.

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

Recent Developments of Our Clinical Programs

Amyotrophic Lateral Sclerosis

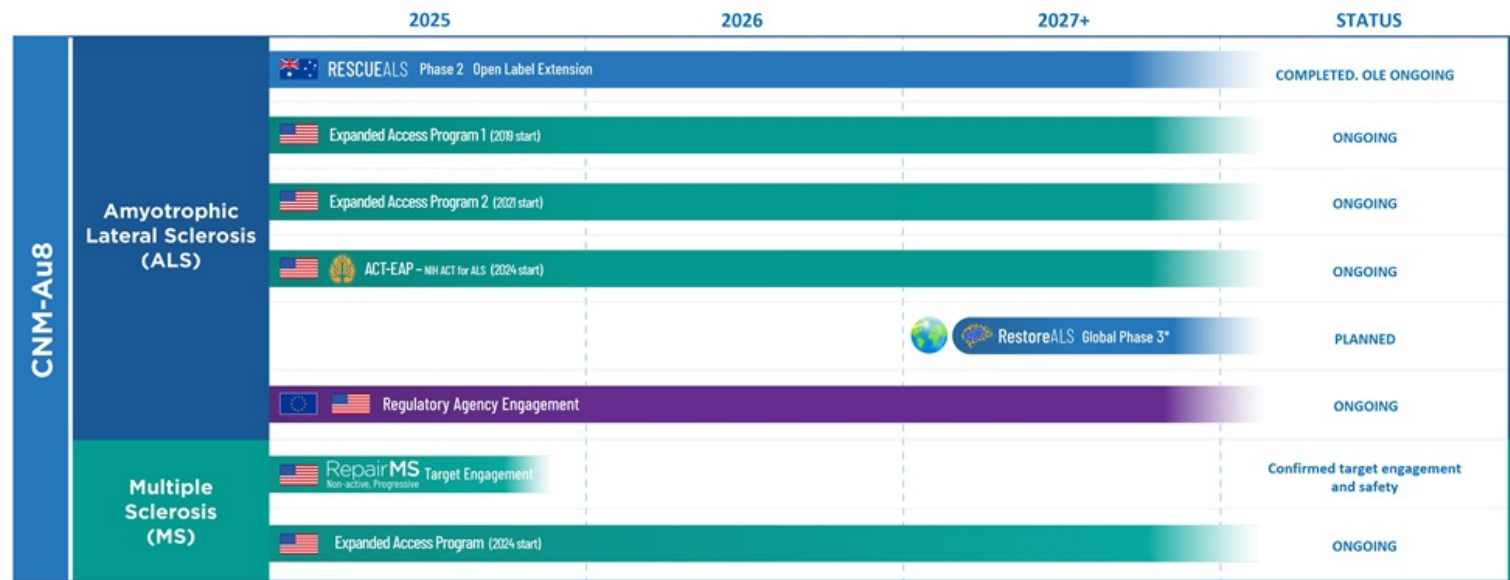
In August 2026, we announced the results from new biomarker analyses examining clinical outcomes among CNM-Au8®-treated patients in our two completed Phase 2 ALS trials. Patients whose neurofilament light chain (“NfL”) biomarker levels declined or stabilized lived significantly longer than concurrently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

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

Multiple Sclerosis

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

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



*Contingent on funding

Financial Overview

Our financial condition, results of operations, and the period-to-period comparability of our financial results are principally affected by the following factors:

Research and Development Expenses

The discovery and development of novel drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been advancing, with substantially all our research and development expenses relating to our lead asset, CNM-Au8.

Our research and development expenses are affected by the scope and advancement of our existing product pipeline and the commencement of new drug programs. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to costs and fees for per patient clinical trial sites for larger clinical trials, opening and monitoring clinical sites, contract research organization (“CRO”) activity, and manufacturing. We anticipate that our research and development expenses will increase in future years if and when we advance our assets into Phase 3. Additionally, if we are able to file an NDA with the FDA under an accelerated approval pathway or subsequent to future Phase 3 clinical development activities, if any, we anticipate that our research and development expenses related to regulatory activities would increase in advance of receiving regulatory approval.

Research and development costs consist primarily of payroll and personnel expenses for salaries, benefits, and stock-based compensation; supplies, materials, and manufacturing expenses to support our clinical trials; payments to CROs, principal investigators, and clinical trial sites; costs of preclinical and nonclinical activities; consulting costs; and allocated overhead costs, including rent, equipment, utilities, depreciation, insurance, maintenance, and information technology. Research and development costs are charged to operations as incurred, and nonrefundable advance payments related to future research and development activities are initially recorded as assets and are expensed when we receive the related goods or services. Grant funding is recognized as a reduction in research and development costs.

Our clinical trial accrual process seeks to account for expenses resulting from obligations under contracts with CROs, consultants, and clinical sites in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We reflect the appropriate clinical trial expenses in the condensed consolidated financial statements by matching the appropriate expenses with the period in which services are performed. In the event advance payments are made to CROs, the payments are recorded as prepaid assets and expensed over the period in which services are performed.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and personnel expenses for salaries, benefits, and stock-based compensation; fees for legal, finance, accounting, tax, and information technology services; insurance costs; expenses for public and investor relations; rent, utilities, depreciation, and other costs related to our facilities.

We anticipate that our general and administrative expenses in future periods will be contingent upon our regulatory pathway with the FDA. If we are able to file an NDA with the FDA under an accelerated approval pathway, we anticipate our general and administrative expenses would increase in future periods to support increases in our drug development activities and as we build our commercial capabilities in advance of receiving regulatory approval. This potential increase will likely include increased headcount, increased stock-based compensation expenses, expanded infrastructure including certain sales and marketing activities performed ahead of regulatory approval, and increased insurance expenses. If we are unable to file an NDA with the FDA under an accelerated approval pathway, or if our NDA is not approved, we would need to continue investing in clinical research activities and we anticipate our general and administrative expenses would decrease in future periods as we decrease commercial manufacturing expansion projects, including at our Elkton, Maryland facility, and as we implement cost-saving initiatives, such as a reduction in compensation, a hiring freeze, and elimination of certain staff positions.

Total Other Income (Expense), Net

Total other income (expense), net, consists primarily of (i) interest income and interest expense, (ii) changes in the fair value of our common stock warrant liabilities and derivative liabilities, (iii) research and development tax credits, unrestricted grants, and conditional grants for which applicable conditions have been met, (iv) issuance costs for common stock warrant liabilities, and (v) losses on initial issuances of equity if the fair value exceeds the proceeds from public equity offerings.

Results of Operations

Our results of operations for the three and six months ended June 30, 2026 and 2025 were as follows:

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	Change	2026	2025	Change
Revenue:						
Product revenue	\$ 74	\$ 1	7,300%	\$ 75	\$ 65	15%
Royalty revenue	16	26	(38)%	30	43	(30)%
Total revenue	90	27	233%	105	108	(3)%
Operating expenses:						
Cost of revenue	36	—	*	36	20	80%
Research and development	3,471	3,514	(1)%	3,800	4,995	(24)%
General and administrative	1,930	2,377	(19)%	3,677	5,033	(27)%
Total operating expenses	5,437	5,891	(8)%	7,513	10,048	(25)%
Loss from operations	(5,347)	(5,864)	(9)%	(7,408)	(9,940)	(25)%
Total other income (expense), net	(8,077)	(1,555)	419%	(14,107)	1,770	*
Net loss	\$ (13,424)	\$ (7,419)	81%	\$ (21,515)	\$ (8,170)	163%

Revenue

Product revenue relates to our dietary supplement products and consists of (i) sales of an aqueous zinc-silver ion dietary (mineral) supplement sold by our wholly-owned subsidiary, dOrbital, Inc., under the trade name “rMetx™ ZnAg Immune Boost,” or under a supply agreement with 4Life under the trade name “Zinc Factor™,” and (ii) sales of KHC46, an aqueous gold dietary (mineral) supplement of very low-concentration, sold under a supply agreement with 4Life under the trade name “Gold Factor™.” Royalty revenue relates to our dietary supplement products and consists of proceeds under an exclusive and royalty-bearing license agreement with 4Life relating to the sale of Gold Factor. During the three and six months ended June 30, 2026 and 2025, changes in product and royalty revenue was due to the timing of purchases and sales of Zinc Factor and Gold Factor by 4Life under the supply and license agreements.

Cost of Revenue

Cost of revenue related to production and distribution costs for the sales of Gold Factor, Zinc Factor, and rMetx dietary supplements.

Research and Development Expenses

Research and development expenses during the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	Change	2026	2025	Change
CNM-Au8:						
Amyotrophic lateral sclerosis	\$ 712	\$ 1,468	(51)%	\$ 1,536	\$ 2,811	(45)%
Multiple sclerosis	37	164	(77)%	107	189	(43)%
Regulatory activities	371	130	185%	567	260	118%
General/preclinical/nonclinical	101	19	432%	121	82	48%
Unallocated:						
Facilities	393	386	2%	784	805	(3)%
Depreciation	336	337	(0)%	674	675	(0)%
Manufacturing	522	187	179%	155	270	(43)%
Research	1	2	(50)%	10	7	43%
Equipment	24	14	71%	84	28	200%
Maintenance	32	32	0%	49	64	(23)%
Information technology	76	54	41%	143	119	20%
Other	16	79	(80)%	33	104	(68)%
Personnel	2,188	2,100	4%	4,211	4,260	(1)%
Stock-based compensation	526	600	(12)%	1,240	1,546	(20)%
Grant revenue as a reduction of research and development expense	(1,864)	(2,058)	(9)%	(5,914)	(6,225)	(5)%
Total research and development	\$ 3,471	\$ 3,514	(1)%	\$ 3,800	\$ 4,995	(24)%

* Not meaningful.

The change in research and development expenses was primarily due to the following:

- (i) a decrease in expenses related to our lead drug candidate, CNM-Au8, primarily due to (A) a decrease in expenses related to our ALS clinical programs, including a decrease in expenses related to our two ongoing expanded access programs (“EAPs”) with Massachusetts General Hospital and our ongoing National Institutes of Health-sponsored compassionate-use EAP (the “ACT-EAP”) and a decrease in expenses for planning activities for our RESTORE-ALS clinical trial; (B) a decrease in expenses related to our MS clinical programs primarily due to a decrease in expenses for our REPAIR-MS clinical trial due to conclusion of the second cohort, partially offset by an increase in expenses for our ongoing MS EAP, (C) an increase in expenses for regulatory activities primarily driven by higher expenses related to our ongoing FDA discussions and NDA submission-related activities, and (D) an increase in pre-clinical, non-clinical, and other general CNM-Au8-related expenses;

- (ii) an increase in unallocated expenses during the three months ended June 30, 2026, primarily due to (A) an increase in manufacturing expenses primarily due to use of gold lots purchased at higher commodity prices to manufacture CNM-Au8, and (B) an increase in equipment-related expenses, partially offset by (C) a decrease in other miscellaneous expenses;
- (iii) a decrease in unallocated expenses during the six months ended June 30, 2026, primarily due to (A) an offset to manufacturing expense due to reprocessing multiple gold lots by our supplier when the commodity price of gold increased compared to the original purchase prices, and (B) a decrease in other miscellaneous expenses, partially offset by (C) an increase in equipment-related expenses;
- (iv) an increase in personnel expenses during the three months ended June 30, 2026, primarily due to higher expenses related to the ACT-EAP and our regulatory and NDA submission-related activities; and a decrease in personnel expenses during the six months ended June 30, 2026, primarily due to cost-saving initiatives, partially offset by higher expenses related to the ACT-EAP and our regulatory and NDA submission-related activities;
- (v) a decrease in stock-based compensation expense, primarily due to the timing of award grants, vesting, and forfeitures for research and development personnel; and
- (vi) a decrease in grant revenue, which is recorded as a reduction to research and development expense, due to a decrease in overall reimbursable research and development expenses in the ACT-EAP.

General and Administrative Expenses

General and administrative expenses during the three and six months ended June 30, 2026 and 2025 were as follows:

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	Change	2026	2025	Change
Insurance	\$ 177	\$ 181	(2)%	\$ 328	\$ 362	(9)%
Legal	144	175	(18)%	195	323	(40)%
Finance and accounting	155	220	(30)%	488	530	(8)%
Public and investor relations	109	119	(8)%	202	230	(12)%
Facilities	30	31	(3)%	63	61	3%
Depreciation	17	29	(41)%	34	95	(64)%
Information technology	40	47	(15)%	62	96	(35)%
Personnel	779	788	(1)%	1,417	1,620	(13)%
Stock-based compensation	514	767	(33)%	1,112	1,768	(37)%
Grant revenue as a reduction of general and administrative expense	(93)	(65)	43%	(329)	(228)	44%
Other	58	85	(32)%	105	176	(40)%
Total general and administrative	<u>\$ 1,930</u>	<u>\$ 2,377</u>	<u>(19)%</u>	<u>\$ 3,677</u>	<u>\$ 5,033</u>	<u>(27)%</u>

The change in general and administrative expenses was primarily due to the following:

- (i) a decrease in insurance expenses, primarily due to a decrease in fees for clinical trial, product liability, property, and casualty insurance, partially offset by an increase in fees for directors' and officers' insurance;
- (ii) a decrease in legal fees, primarily due to a decrease in legal fees related to intellectual property, public company compliance, financing and fundraising, and other general corporate legal fees;
- (iii) a decrease in finance and accounting expenses, primarily due to a decrease in audit and tax fees and fees for consultants, advisors, and other financial vendors;
- (iv) a decrease in fees related to our public and investor relations efforts;
- (v) a decrease in depreciation expense due to certain assets reaching the end of their depreciable life;
- (vi) a decrease in information technology-related expenses, primarily due to a decrease in expenses related to maintenance, subscriptions, managed services, and security;
- (vii) a decrease in personnel expenses, primarily due to cost-saving initiatives;

- (viii) a decrease in stock-based compensation expense, primarily due to the timing of award grants, vesting, and forfeitures for general and administrative personnel;
- (ix) an increase in grant revenue, which is recorded as a reduction to general and administrative expense, due to an increase in reimbursable general and administrative expenses in the ACT-EAP; and
- (x) a decrease in other expenses related to lobbying activities and other miscellaneous expenses.

Total Other Income (Expense), Net

Total other income (expense), net, during the three and six months ended June 30, 2026 and 2025 was as follows:

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	Change	2026	2025	Change
Interest income	\$ 55	\$ 62	(11)%	\$ 102	\$ 143	(29)%
Interest expense	(695)	(679)	2%	(1,486)	(1,287)	15%
Issuance costs for common stock warrant liabilities	—	—	*	(393)	—	*
Loss on initial issuance of equity	—	—	*	(4,582)	—	*
Change in fair value of common stock warrant liabilities	(4,132)	(515)	702%	(5,192)	1,995	*
Change in fair value of derivative liabilities	(3,333)	(439)	659%	(2,620)	708	*
Research and development tax credits and unrestricted grants	28	16	75%	64	211	(70)%
Total other income (expense), net	\$ (8,077)	\$ (1,555)	419%	\$ (14,107)	\$ 1,770	*

* Not meaningful.

The change in total other income (expense), net, was primarily due to the following:

- (i) a decrease in interest income primarily due to lower average balances of cash and cash equivalents and lower interest rates in 2026;
- (ii) an increase in interest expense primarily due to the senior secured convertible promissory notes issued in August 2025;
- (iii) issuance costs from a public equity offering allocated to liability-classified warrants during the six months ended June 30, 2026;
- (iv) a loss on initial issuance of equity from the fair value in excess of proceeds from a public equity offering during the six months ended June 30, 2026;
- (v) a loss from the changes in fair value of common stock warrant liabilities during the three and six months ended June 30, 2026 and three months ended June 30, 2025, and a gain during the six months ended June 30, 2025. The changes in fair value were due to changes in price of our common stock and updates in valuation model assumptions (see “Critical Accounting Estimates”);
- (vi) a loss from the change in fair value of the derivative liabilities separated from our senior secured convertible promissory notes during the three and six months ended June 30, 2026 and three months ended June 30, 2025, and a gain during the six months ended June 30, 2025. The changes in fair value were due to changes in price of our common stock and updates in valuation model assumptions (see “Critical Accounting Estimates”);
- (vii) a decrease in research and development tax credits and unrestricted grants during the six months ended June 30, 2026, due to the receipt of Maryland tax credits during the six months ended June 30, 2025, that were not received during the six months ended June 30, 2026.

Taxation

United States

We are incorporated in the state of Delaware and subject to statutory U.S. federal corporate income tax at a rate of 21.00%. We are also subject to state income tax in Maryland at a rate of 8.25%, and in Utah at a rate of 4.50%. As of June 30, 2026 and December 31, 2025, we recorded a full valuation allowance against our net deferred tax assets due to the uncertainty as to whether such assets will be realized resulting from our three-year cumulative loss position and the uncertainty surrounding our ability to generate pre-tax income in the foreseeable future.

Australia

Our wholly-owned subsidiary, Clene Australia Pty Ltd (“Clene Australia”), was established in Australia in March 2018 and is subject to corporate income tax at a rate of 30.00%. Clene Australia had no taxable income or provision for income taxes for the six months ended June 30, 2026 and 2025. We recorded other income of \$64,000 and \$40,000 for the six months ended June 30, 2026 and 2025, respectively, for research and development tax credits pertaining to Clene Australia for the 2026 and 2025 tax years, respectively.

Netherlands

Our wholly-owned subsidiary, Clene Netherlands B.V. (“Clene Netherlands”), was established in the Netherlands in April 2021 and is subject to corporate income tax at a rate of 19.00% up to €200,000 of taxable income and 25.80% for taxable income in excess of €200,000 for the six months ended June 30, 2026 and 2025. Clene Netherlands had no taxable income or provision for income taxes for the six months ended June 30, 2026 and 2025.

Liquidity and Capital Resources

Sources of Capital

We have incurred significant losses and negative cash flows from operations since our inception. We expect to incur additional losses in the future to fund our operations and conduct research and development of our drug candidates. We recognize the need to raise additional capital to fully implement our business plan. The long-term continuation of our business plan is dependent upon the generation of sufficient revenue from our products to offset expenses and capital expenditures. In the event that we do not generate sufficient revenue and are unable to obtain funding, we will be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion, commercialization efforts, or capital expenditures, which could adversely affect our business prospects, ability to meet long-term liquidity needs, or we may be unable to continue operations.

Since our inception, we have dedicated substantially all our resources to the development of our drug candidates. We have financed our operations principally through the following sources:

- gross proceeds of \$209.6 million from equity financing, including sales of common stock, preferred stock, common stock warrants, and pre-funded common stock warrants;
- gross proceeds of \$71.1 million from borrowings under notes payable, convertible notes payable, and convertible promissory notes;
- gross proceeds of \$9.4 million from our reverse recapitalization whereby we became a public company;
- gross proceeds of \$10.2 million from refundable research and development tax credits;
- gross proceeds of \$20.0 million from grants from various organizations; and
- gross proceeds of \$1.1 million from stock option and warrant exercises.

We also received indirect financial support for the HEALEY ALS Platform Trial, administered by Massachusetts General Hospital, which conducted an ALS platform trial of CNM-Au8 alongside multiple other drug candidates, at significantly lower costs than we would have otherwise incurred if we had conducted a comparably designed clinical trial at reasonable market rates.

Going Concern

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

We have incurred significant losses and negative cash flows from operations since our inception. We have not generated significant revenue since our inception, and we do not anticipate generating significant revenue unless we successfully complete development and obtain regulatory approval for commercialization of a drug candidate. We expect to incur additional losses in the future, particularly as we advance the development of our clinical-stage drug candidates, continue research and development of our preclinical drug candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our senior secured convertible promissory notes issued in December 2024 (the “2024 SSCP Notes”), we are required to maintain unrestricted cash and cash equivalents of at least \$2.0 million to avoid acceleration of the full balance of the 2024 SSCP Notes (see Note 8 to the condensed consolidated financial statements). These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

To mitigate our funding needs, we plan to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as utilizing our existing at-the-market facility and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the three and six months ended June 30, 2026, we raised \$7.0 million and \$13.0 million, respectively, of gross proceeds from registered direct offerings of equity securities (see Note 13 to the condensed consolidated financial statements). While we have implemented cost-saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts, reducing employee compensation, and eliminating certain staff positions, we have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date the condensed consolidated financial statements contained in this report are issued.

The accompanying condensed consolidated financial statements 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, the accompanying condensed consolidated financial statements 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.

Short-Term Material Cash Requirements

For at least the next twelve months, our primary capital requirements are to fund our operations, including research and development, personnel, regulatory, and other clinical trial costs related to development of our lead drug candidate, CNM-Au8; general and administrative costs to support our drug development and pre-commercial activities in advance of receiving regulatory approval for our drug candidates; and principal and interest payments on our notes payable and convertible notes payable. Firm commitments for funds include approximately \$1.1 million of payments under operating lease obligations, payment of principal and interest on notes payable and convertible notes payable totaling \$0.7 million, and a commitment for capital expenditures totaling \$1.6 million related to the construction of our manufacturing facilities. We expect to meet our short-term liquidity requirements primarily through cash on hand. Additional sources of funds include equity financing, debt financing, or other capital sources. However, there can be no assurance that we will be able to secure such financing on favorable terms, or at all.

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, subject to payment of our remaining obligations under binding purchase orders and, in certain cases, nominal early termination fees. These commitments are not deemed significant.

Long-Term Material Cash Requirements

Beyond the next twelve months, our primary capital requirements are to fund our operations, including research and development, personnel, regulatory, and other clinical trial costs related to development of our lead drug candidate, CNM-Au8; general and administrative costs to support our drug development activities in advance of receiving regulatory approval for our drug candidates; and principal and interest payments on our notes payable and convertible notes payable. Additional funds may be spent to initiate new clinical trials, at our discretion. Known obligations beyond the next twelve months include \$3.4 million of payments under operating lease obligations, and interest and principal repayment of notes payable and convertible notes payable of \$21.2 million. We expect to meet our long-term liquidity requirements primarily through equity financing, debt financing, or other capital sources. However, there can be no assurance that we will be able to secure such financing on favorable terms, or at all.

Use of Funds

Our cash flows for the six months ended June 30, 2026 and 2025 were as follows:

(in thousands)	Six Months Ended June 30,	
	2026	2025
Net cash used in operating activities	\$ (7,116)	\$ (9,755)
Net cash used in investing activities	(1)	—
Net cash provided by financing activities	11,563	4,806
Effect of foreign exchange rate changes on cash	36	79
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 4,482	\$ (4,870)

Our primary use of cash in all periods presented was to fund our research and development, regulatory and other clinical trial costs, and general corporate expenditures.

Operating Activities

Net cash used in operating activities was \$7.1 million for the six months ended June 30, 2026, which resulted from a net loss of \$21.5 million, adjusted for non-cash items totaling \$17.5 million and a net change in operating assets and liabilities of \$3.1 million. Significant non-cash items included: (i) depreciation expense of \$0.7 million related to laboratory and office equipment and leasehold improvements, (ii) non-cash lease expense of \$0.3 million, (iii) stock-based compensation expense of \$2.4 million, (iv) accretion of debt discount of \$0.5 million, (v) non-cash interest expense on notes payable of \$0.8 million, (vi) issuance costs for common stock warrant liabilities of \$0.4 million, (vii) a loss on initial issuance of equity from the fair value in excess of proceeds from a public equity offering of \$4.6 million, (viii) a change in fair value of our common stock warrant liabilities of \$5.2 million due to changes in the price of our common stock and changes in valuation model inputs, and (ix) a change in fair value of our derivative liabilities of \$2.6 million due to changes in the price of our common stock and changes in valuation model inputs. The net change in operating assets and liabilities was primarily attributable to: (i) an increase in accounts receivable of \$43,000 and an increase in accounts payable of \$0.3 million due to the timing of vendor invoicing and payments, (ii) an increase in prepaid expenses and other current assets of \$1.4 million due to (A) the timing of vendor invoicing and payments, (B) an increase in metals to be used in research and development due to the timing of invoicing, payments, and deliveries from our supplier, and changes in the commodity price of gold during reprocessing by our supplier compared to the original purchase price, (C) an increase in grants receivable related to ACT-EAP reimbursements, and (D) an increase in prepaid clinical and CRO expenses related to the ACT-EAP, partially offset by (E) a decrease in research and development tax credits receivable due to the timing of refund payments, and (F) a decrease in miscellaneous prepaids and other current assets, (iii) a decrease in accrued liabilities of \$1.4 million primarily due to (A) a decrease in accrued compensation and benefits resulting from payments of deferred employee bonuses in cash and equity, (B) a decrease in deferred grants due to satisfaction of grant conditions or performance obligations, and (C) a decrease in other miscellaneous accrued liabilities, partially offset by (D) an increase in accrued CRO and clinical fees related to our ongoing clinical programs, and (iv) a decrease in operating lease obligations of \$0.4 million.

Net cash used in operating activities was \$9.8 million for the six months ended June 30, 2025, which resulted from a net loss of \$8.2 million, adjusted for non-cash items totaling \$2.2 million and a net change in operating assets and liabilities of \$3.8 million. Significant non-cash items included: (i) depreciation expense of \$0.8 million related to laboratory and office equipment and leasehold improvements, (ii) non-cash lease expense of \$0.3 million, (iii) stock-based compensation expense of \$3.3 million, (iv) accretion of debt discount of \$0.5 million, (v) non-cash interest expense on notes payable of \$24,000, (vi) a change in fair value of our common stock warrant liabilities of \$2.0 million due to changes in the price of our common stock and changes in valuation model inputs, and (vii) a change in fair value of the our derivative liabilities of \$0.7 million due to changes in the price of our common stock and changes in valuation model inputs. The net change in operating assets and liabilities was primarily attributable to: (i) a decrease in accounts receivable of \$0.1 million and a decrease in accounts payable of \$0.4 million due to the timing of vendor invoicing and payments, (ii) an increase in prepaid expenses and other current assets of \$0.8 million due to (A) the timing of vendor invoicing and payments, (B) the timing of receipt of metals to be used in research and development, and (C) an increase in research and development tax credits receivable, partially offset by (D) a decrease in prepaid clinical and CRO expenses related to the ACT-EAP, (iii) a decrease in accrued liabilities of \$2.3 million primarily due to (A) a decrease in deferred grants, and (B) a decrease in other miscellaneous accrued liabilities, partially offset by (C) an increase in accrued compensation and benefits, and (iv) a decrease in operating lease obligations of \$0.3 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2026 consisted of purchases of property and equipment of \$1,000. We had no net cash provided by or used in investing activities during the six months ended June 30, 2025.

Financing Activities

Net cash provided by financing activities was \$11.6 million for the six months ended June 30, 2026, which consisted of proceeds from the issuance of common stock and warrants, net of offering costs, of \$11.7 million, partially offset by payments of notes payable of \$0.2 million. Net cash provided by financing activities was \$4.8 million for the six months ended June 30, 2025, which consisted of proceeds from the issuance of common stock of \$5.0 million, partially offset by payments of notes payable of \$0.2 million.

Public Offerings

In January 2026, pursuant to a placement agency agreement with BTIG, LLC (“BTIG”), we sold 928,333 shares of our common stock, warrants to purchase up to 1,114,000 shares of our common stock (the “Series A Warrants”), and warrants to purchase up to 2,599,333 shares of our common stock (the “Series B Warrants”). The aggregate gross proceeds were approximately \$6.0 million, of which \$0.3 million was contributed by certain of our directors and their affiliated entities, excluding the proceeds, of any, from the exercise of the Series A Warrants and Series B Warrants and before deducting placement agent fees and expenses and other expenses payable by us. We paid BTIG a placement agent fee of 6.00% of the aggregate gross proceeds of the offering. The offering was made pursuant to our registration statement on Form S-3 (file number 333-286058), declared effective on April 25, 2025 (the “2025 S-3”), and a related prospectus supplement.

In May 2026, pursuant to an underwriting agreement with Canaccord Genuity LLC, we sold 1,000,000 shares of our common stock at an offering price of \$7.00 per share. The aggregate gross proceeds were \$7.0 million. We paid underwriting discounts and commissions of \$0.5 million and other offering expenses of \$0.1 million. The offering was made pursuant to our 2025 S-3 and a prospectus supplement related to the offering.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles. The preparation of these condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, revenues, costs, and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones, and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We consider the following estimates to be critical as they involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition and results of operations.

Convertible Notes

In accordance with ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, we classified the 2022 DHCD Loan as convertible notes payable in the condensed consolidated balance sheets and did not separate the conversion option from the host contract as it did not meet the requirements for accounting as a derivative instrument. We account for the convertible note as a single liability measured at its amortized cost as of June 30, 2026 and December 31, 2025, with a carrying value of \$5.3 million and \$5.3 million, respectively.

We classified a portion of the senior secured convertible promissory notes (the “SSCP Notes”) as convertible notes payable in the consolidated balance sheets and separated three features from the host contract as derivative instruments measured at fair value: (i) the conversion option (the “SSCPN Conversion Feature”), (ii) the redemption option upon a change of control or any bankruptcy, liquidation, or other restructuring process consisting of a cash payment equal to 115% of the outstanding principal (the “SSCPN Redemption Feature”), and (iii) the acceleration option plus a penalty equal to 10% of all outstanding principal and accrued and unpaid interest upon the occurrence and continuation of certain events of default (the “SSCPN Default Feature,” collectively with the SSCP Conversion Feature and SSCP Redemption Feature, the “SSCPN Derivative Liabilities”). We accounted for the remainder of the SSCP Notes as liabilities measured at their amortized cost, with carrying values of (i) \$10.4 million and \$9.3 million for the 2024 SSCP Notes as of June 30, 2026 and December 31, 2025, respectively, and (ii) \$1.5 million and \$1.4 million for the 2025 SSCP Notes as of June 30, 2026 and December 31, 2025, respectively.

We remeasure the SSCP Derivative Liabilities at each reporting date and record the change in fair value as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The change in fair value of the SSCP Derivative Liabilities resulted in a loss of \$3.3 million and a loss of \$0.4 million during the three months ended June 30, 2026 and 2025, respectively; and a loss of \$2.6 million and a gain of \$0.7 million during the six months ended June 30, 2026 and 2025, respectively. We estimate the fair value of the SSCP Notes with and without the SSCP Derivative Liabilities and calculate the difference as the implied fair value of the SSCP Derivative Liabilities. The valuation model consists of a discounted cash flow model and a Black-Scholes option-pricing model with probability weights for the occurrence of (i) a change of control transaction, (ii) default of the Company, or (iii) held to maturity. These estimates require significant judgment. The unobservable valuation inputs were as follows:

	June 30, 2026	May 18, 2026 ⁽¹⁾	May 18, 2026 ⁽²⁾	May 11, 2026 ⁽³⁾	May 11, 2026 ⁽⁴⁾	December 31, 2025
Expected stock price volatility	114.20%	113.30%	120.50%	112.60%	120.40%	107.30%
Discount rate	20.00%	20.00%	20.00%	20.00%	20.00%	19.00%
Risk-free interest rate	4.00%	3.90%	3.70% – 3.80%	3.80%	3.70% – 3.80%	3.50% – 3.60%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Expected term (in years)	0.21 – 1.12	0.41 – 1.24	0.32 – 0.74	0.43 – 1.26	0.34 – 0.76	0.38 – 1.12
Probability of change of control	30.00%	30.00%	5.00%	30.00%	5.00%	20.00%
Probability of default	5.00%	5.00%	5.00%	5.00%	5.00%	35.00%
Probability of held to maturity	65.00%	65.00%	90.00%	65.00%	90.00%	45.00%

(1) Represents the unobservable inputs to the valuation of the SSCP Derivative Liabilities related to the 2025 SSCP Notes immediately following an amendment in May 2026.

(2) Represents the unobservable inputs to the valuation of the SSCP Derivative Liabilities related to the 2025 SSCP Notes immediately preceding an amendment in May 2026.

(3) Represents the unobservable inputs to the valuation of the SSCP Derivative Liabilities related to the 2024 SSCP Notes immediately following an amendment in May 2026.

(4) Represents the unobservable inputs to the valuation of the SSCP Derivative Liabilities related to the 2024 SSCP Notes immediately preceding an amendment in May 2026.

Common Stock Warrant Liabilities

In accordance with ASC 815, we recognized the below common stock warrants as derivative liabilities measured at fair value and will remeasure them at each reporting date and record the change in fair value as a component of other income (expense), net, in the condensed consolidated statements of operations and comprehensive loss.

Pursuant to a loan with Avenue Venture Opportunities Fund, L.P. (“Avenue”), which we repaid in 2024, we issued a warrant to purchase 150,000 shares of our common stock at \$4.6014 per share (the “2023 Avenue Warrant”). The change in fair value of the 2023 Avenue Warrant resulted in a loss of \$0.1 million and a loss of \$25,000 during the three months ended June 30, 2026 and 2025, respectively; and a loss of \$0.1 million and a gain of \$0.1 million during the six months ended June 30, 2026 and 2025, respectively. We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of (i) settlement of the instrument upon a change of control transaction, (ii) dissolution of the Company, or (iii) held to expiration. These estimates require significant judgment. The unobservable valuation inputs were as follows:

	June 30, 2026	December 31, 2025
Expected stock price volatility	107.00% – 115.40%	104.40% – 119.00%
Risk-free interest rate	4.00% – 4.10%	3.50% – 3.60%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	1.09 – 2.00	0.50 – 2.50
Probability of change of control	30.00%	20.00%
Probability of dissolution	30.00%	35.00%
Probability of held to expiration	40.00%	45.00%

Pursuant to an underwritten public offering in June 2023, we issued warrants to purchase 2,500,000 shares of our common stock at \$22.00 per share (the “Tranche A Warrants”). The Tranche A Warrants expired unexercised in June 2026. The change in fair value prior to the expiration of the Tranche A Warrants resulted in a loss of \$30,000 during the three months ended June 30, 2025, and a gain of \$0.4 million and a gain of \$0.6 million during the six months ended June 30, 2026 and 2025, respectively. We estimated the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of (i) acceptance of an NDA by the FDA for CNM-Au8, (ii) settlement upon a fundamental transaction, (iii) dissolution of the Company, and (iv) held to expiration. These estimates required significant judgment. The unobservable valuation inputs were as follows:

	December 31, 2025
Expected stock price volatility	124.00%
Risk-free interest rate	3.60%
Expected dividend yield	0.00%
Expected term (in years)	0.46
Probability of NDA acceptance before warrant expiration	0.00%
Probability of fundamental transaction before warrant expiration	0.00%
Probability of dissolution before warrant expiration	35.00%
Probability of held to expiration	65.00%

Pursuant to a registered direct public offering in October 2024, we issued warrants to purchase 1,546,914 shares of our common stock at \$4.82 per share (the “2024 Common Warrants”). The change in fair value of the 2024 Common Warrants resulted in a loss of \$1.0 million and a loss of \$0.5 million during the three months ended June 30, 2026 and 2025, respectively; and a loss of \$0.3 million and a gain of \$1.3 million during the six months ended June 30, 2026 and 2025, respectively. We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of (i) dissolution of the Company and (ii) held to maturity. These estimates require significant judgment. The unobservable valuation inputs were as follows:

	June 30, 2026	December 31, 2025
Expected stock price volatility	100.90%	104.30%
Risk-free interest rate	4.20%	3.60%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	3.25	3.75
Probability of dissolution	30.00%	35.00%
Probability of held to expiration	70.00%	65.00%

Pursuant to a registered direct public offering in January 2026, we issued Series A Warrants to purchase 1,114,000 shares of our common stock at \$6.00 per share. The exercise price of the Series A Warrants will increase to \$7.00 per share if (i) the Series A Warrant is exercised prior to our public announcement of the FDA's posted action date under the Prescription Drug User Fee Act for our NDA for CNM-Au8 (the "Series A Trigger Announcement"), or (ii) the volume weighted average price ("VWAP") of our common stock equals or exceeds \$10.00 on the Series A Price Measurement Date, as defined below. The "Series A Price Measurement Date" means (A) the trading day on which the Series A Trigger Announcement is made, if such announcement is made prior to 9:00 a.m. (New York City time) on such trading day, or (B) the first trading day immediately following the day on which the Series A Trigger Announcement is made, if such announcement is made at or after 9:01 a.m. (New York City time) on a trading day or on a day that is not a trading day.

The change in fair value of the Series A Warrants resulted in a loss of \$0.6 million and a loss of \$0.9 million during the three and six months ended June 30, 2026. We estimate the fair value using a Monte Carlo simulation with estimates for (i) the probability of the Series A Trigger Announcement (ii) the expected stock price increase if the Series A Trigger Announcement occurs, and (iii) the expected stock price decrease if the Series A Trigger Announcement does not occur. These estimates require significant judgment. The unobservable valuation inputs were as follows:

	June 30, 2026	January 13, 2026
Expected stock price volatility	102.60%	107.30%
Risk-free interest rate	4.10%	3.68%
Expected term (in years)	0.42 – 2.54	0.46 – 3.00
Probability of Series A Trigger Announcement	50.00%	35.00%
Expected stock price increase if Series A Trigger Announcement occurs	35.00%	35.00%
Expected stock price decrease if Series A Trigger Announcement does not occur	85.00%	85.00%

Pursuant to a registered direct public offering in January 2026, we issued Series B Warrants to purchase 2,599,333 shares of our common stock at \$6.00 per share. The exercise price of the Series B Warrants will increase to (i) \$10.00 per share if the VWAP of our common stock equals or exceeds \$20.00 on the Series B Price Measurement Date, or (ii) \$12.50 per share if (A) the VWAP of our common stock equals or exceeds \$25.00 on the Series B Price Measurement Date, or (B) the Series B Warrant is exercised prior to our public announcement of receipt of written approval from the FDA of our NDA for CNM-Au8 in ALS, which announcement shall be made promptly after receipt of such approval (the "Series B Trigger Announcement"). The "Series B Price Measurement Date" means (A) the trading day on which the Series B Trigger Announcement is made, if such announcement is made prior to 9:00 a.m. (New York City time) on such trading day, or (B) the first trading day immediately following the day on which the Series B Trigger Announcement is made, if such announcement is made at or after 9:01 a.m. (New York City time) on a trading day or on a day that is not a trading day.

The change in fair value of the Series B Warrants resulted in a loss of \$2.4 million and a loss of \$4.3 million during the three and six months ended June 30, 2026. We estimate the fair value using a Monte Carlo simulation with estimates for (i) the probability of the Series B Announcement (ii) the expected stock price increase if the Series B Trigger Announcement occurs, and (iii) the expected stock price decrease if the Series B Trigger Announcement does not occur. These estimates require significant judgment. The unobservable valuation inputs were as follows:

	June 30, 2026	January 13, 2026
Expected stock price volatility	102.60%	107.30%
Risk-free interest rate	4.10%	3.68%
Expected term (in years)	0.92 – 4.54	0.96 – 5.00
Probability of Series B Trigger Announcement	35.00%	24.00%
Expected stock price increase if Series B Trigger Announcement occurs	100.00%	100.00%
Expected stock price decrease if Series B Trigger Announcement does not occur	95.00%	95.00%

Income Taxes

We record uncertain tax positions in accordance with ASC 740, *Income Taxes*, on the basis of a two-step process to (i) determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position, and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize deferred tax assets to the extent we believe these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and recent results of operations. If we determine that we would be able to realize any deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The estimation of these factors requires significant judgment. Based on our evaluation of these factors, we have not recorded income tax benefits for the net operating losses or for research and development tax credits or other deferred tax assets due to uncertainty of realizing benefits from these items.

Stock-Based Compensation

We account for stock-based compensation arrangements using a fair value-based method for costs related to all share-based payments including stock options and stock awards. The fair value is recognized over the period during which a grantee was required to provide services in exchange for the option award and service-based stock awards, known as the requisite service period (usually the vesting period), on a straight-line basis. For stock awards with market conditions, the fair value is recognized over the period based on the expected milestone achievement dates as the derived service period (usually the vesting period), on a straight-line basis. For stock awards with performance conditions, the grant-date fair value of these awards is the market price on the applicable grant date, and compensation expense will be recognized when the conditions become probable of being satisfied. We will recognize a cumulative true-up adjustment once the conditions become probable of being satisfied as the related service period had been completed in a prior period. We elect to account for forfeitures as they occur, rather than estimating expected forfeitures.

We estimate the fair value of stock options using a Black-Scholes option-pricing model, which requires significant judgment. The unobservable valuation inputs were as follows:

	Six Months Ended June 30,	
	2026	2025
Expected stock price volatility	96.64% – 107.55%	103.78% – 110.25%
Risk-free interest rate	3.65% – 4.27%	4.05% – 4.24%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 – 6.09	5.00 – 6.25

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide information required by this Item.

Item 4. Controls and Procedures**Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2026, as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the “Exchange Act”). As a result of this evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2026, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting described below. Notwithstanding the identified material weaknesses, management, including our principal executive officer and principal financial officer, believes the condensed consolidated financial statements included in this Quarterly Report fairly represent, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with U.S. Generally Accepted Accounting Principles.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Material Weaknesses in Internal Control over Financial Reporting

In connection with the audit of our financial statements as of and for the years ended December 31, 2025 and 2024, our management identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified relate to the fact that we did not design or maintain an effective control environment commensurate with our financial reporting requirements. This deficiency in our control environment contributed to the following additional material weaknesses related to control activities and information and communication within our internal control over financial reporting:

- we did not design and maintain controls over the preparation and review of reconciliations and the review and segregation of duties over manual journal entries, including controls over the completeness and accuracy of information; and
- we did not design and maintain information technology (“IT”) general controls for IT systems that are relevant to the preparation of the financial statements. Specifically, we did not design and maintain: (a) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to our appropriate personnel; (b) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized, and implemented appropriately; (c) computer operations controls to ensure that data backups are authorized and monitored; and (d) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

Each of the control deficiencies described above could result in a misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that each of the control deficiencies described above constitute material weaknesses.

Material Weakness Remediation

Management continues to be actively engaged and committed to taking the steps necessary to remediate the control deficiencies that constituted the above material weaknesses. During 2025, we made the following enhancements to our control environment:

- we strengthened the experience of our internal accounting team through refinement of our processes and internal controls over financial reporting and our IT and technical accounting resources; and
- until we have sufficient technical accounting resources, we engaged external consultants to provide support and to assist us in our evaluation of more complex applications of GAAP.

Our remediation activities are continuing during 2026. In addition to the above actions, we expect to engage in additional activities, or have completed additional activities, including, but not limited to:

- adding more technical accounting resources to enhance our control environment; and
- until we have sufficient technical accounting resources, engaging external consultants to provide support and to assist us in our evaluation of more complex applications of GAAP.

We continue to enhance corporate oversight over process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability to enable remediation of our material weaknesses. We believe that our remediation plan will be sufficient to remediate the identified material weaknesses and strengthen our internal control over financial reporting. As we continue to evaluate, and work to improve, our internal control over financial reporting, management may determine that additional measures to address control deficiencies or modifications to the remediation plan are necessary.

Changes in Internal Control over Financial Reporting

Other than changes described under “—*Material Weakness Remediation*,” above there were no changes in our internal control over financial reporting during the quarter ended June 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material pending legal proceedings. From time to time, we may, however, be involved in legal proceedings in the ordinary course of business. We cannot predict the outcome of any such legal proceedings, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Our business, financial condition, and results of operations can be affected by a number of factors, whether currently known or unknown, including, but not limited to, those described in Part I, Item 1A, Risk Factors of our 2025 Annual Report on Form 10-K, which was filed with the SEC on March 17, 2026. There have been no material changes to the risk factors since previously disclosed in the 2025 Annual Report on Form 10-K. Any one or more of these factors could, directly or indirectly, cause our actual financial condition and results of operations to vary materially from past, or from anticipated future, financial condition and results of operations. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds

None.

(c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

During the three months ended June 30, 2026, none of our officers or directors adopted or terminated any “Rule 10b5-1 trading arrangement” or any “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit Description
1.1	Underwriting Agreement, dated May 5, 2026, by and between Clene Inc. and Canaccord Genuity LLC (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed by the registrant on May 5, 2026).
3.1	Fourth Amended and Restated Certificate of Incorporation of Clene Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the registrant on May 11, 2023).
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Clene Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the registrant on May 30, 2024).
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Clene Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the registrant on July 9, 2024).
3.4	Bylaws of Clene Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Registrant on January 5, 2021).
10.1	Letter Agreement, dated April 22, 2026, by and between Clene Inc. and 4Life Research, LLC (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed by the registrant on May 14, 2026).
10.2	Form of Second Amended & Restated Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q filed by the registrant on May 14, 2026).
10.3	Form of Amended & Restated Senior Secured Convertible Promissory Notes (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the registrant on May 22, 2026).
10.4	Clene Inc. Amended 2020 Stock Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the registrant on May 22, 2026).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.

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, thereunto duly authorized.

CLENE INC.

Dated: August 14, 2026

By: /s/ Robert Etherington
Name: Robert Etherington
Title: President, Chief Executive Officer and Director

Dated: August 14, 2026

By: /s/ Morgan R. Brown
Name: Morgan R. Brown
Title: Chief Financial Officer

CERTIFICATION

I, Robert Etherington, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clene Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2026

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

CERTIFICATION

I, Morgan R. Brown, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clene Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2026

/s/ Morgan R. Brown
 Morgan R. Brown
 Chief Financial Officer

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Robert Etherington, President and Chief Executive Officer of Clene Inc. (the “Company”), hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2026, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2026

/s/ Robert Etherington

Robert Etherington

President and Chief Executive Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Morgan R. Brown, Chief Financial Officer of Clene Inc. (the “Company”), hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2026, to which this Certification is attached as Exhibit 32.2 (the “Quarterly Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2026

/s/ Morgan R. Brown

Morgan R. Brown
Chief Financial Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.