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, 2024

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: **01-39834**

CLENE INC.

(Exact name of registrant as specified in its charter)

Delaware	**85-2828339**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6550 South Millrock Drive, Suite G50 Salt Lake City, Utah	**84121**
(Address of principal executive offices)	(Zip Code)

(801) 676-9695
(Registrant's telephone number, including area code)

N/A
(Former name, 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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	CLNN	The Nasdaq Capital Market
Warrants, to acquire one-fortieth of one share of Common Stock for $230.00 per share	CLNNW	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 5, 2024 was 6,470,067.

CLENE INC.
Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2024

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, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,682	$ 28,821
Marketable securities	—	6,179
Accounts receivable	—	143
Inventory	37	37
Prepaid expenses and other current assets	6,191	3,672
Total current assets	27,910	38,852
Restricted cash	58	58
Operating lease right-of-use assets	3,920	4,168
Property and equipment, net	8,442	9,263
TOTAL ASSETS	$ 40,330	$ 52,341
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,066	$ 1,504
Accrued liabilities	5,927	3,720
Operating lease obligations, current portion	623	576
Finance lease obligations, current portion	—	27
Notes payable, current portion	20,453	14,627
Convertible notes payable, current portion	—	4,876
Total current liabilities	28,069	25,330
Operating lease obligations, net of current portion	4,530	4,903
Notes payable, net of current portion	1,745	1,894
Convertible notes payable, net of current portion	5,268	5,258
Common stock warrant liabilities	1,222	1,481
Clene Nanomedicine contingent earn-out liability	—	75
Initial Stockholders contingent earn-out liability	—	10
TOTAL LIABILITIES	40,834	38,951
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 600,000,000 and 300,000,000 shares authorized at June 30, 2024 and December 31, 2023, respectively; 6,433,628 and 6,421,084 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	259,913	255,913
Accumulated deficit	(260,588)	(242,723)
Accumulated other comprehensive income	170	199
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(504)	13,390
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 40,330	$ 52,341

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,	
	2024	2023	2024	2023
Revenue:				
Product revenue	$ 64	$ 226	$ 108	$ 290
Royalty revenue	27	43	56	86
Total revenue	91	269	164	376
Operating expenses:				
Cost of revenue	18	66	34	71
Research and development	4,150	6,615	10,019	14,010
General and administrative	3,314	3,924	6,734	7,363
Total operating expenses	7,482	10,605	16,787	21,444
Loss from operations	(7,391)	(10,336)	(16,623)	(21,068)
Other income (expense), net:				
Interest income	269	213	628	385
Interest expense	(1,282)	(1,104)	(2,526)	(2,170)
Commitment share expense	—	(3)	—	(402)
Issuance costs for common stock warrant liabilities	—	(333)	—	(333)
Loss on initial issuance of equity	—	(14,840)	—	(14,840)
Change in fair value of common stock warrant liabilities	1,568	(383)	259	(383)
Change in fair value of Clene Nanomedicine contingent earn-out liability	22	1,165	75	1,110
Change in fair value of Initial Stockholders contingent earn-out liability	3	150	10	143
Research and development tax credits and unrestricted grants	26	341	312	655
Other expense, net	—	(13)	—	(10)
Total other income (expense), net	606	(14,807)	(1,242)	(15,845)
Net loss before income taxes	(6,785)	(25,143)	(17,865)	(36,913)
Income tax expense	—	—	—	—
Net loss	(6,785)	(25,143)	(17,865)	(36,913)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	2	6	(2)	20
Foreign currency translation adjustments	28	(53)	(27)	(49)
Total other comprehensive income (loss)	30	(47)	(29)	(29)
Comprehensive loss	$ (6,755)	$ (25,190)	$ (17,894)	$ (36,942)
Net loss per share – basic and diluted	$ (1.06)	$ (5.84)	$ (2.78)	$ (9.11)
Weighted average common shares used to compute basic and diluted net loss per share	6,423,182	4,302,520	6,422,242	4,053,883

See accompanying notes to the condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2023	6,421,084	$ 1	$ 255,913	$ (242,723)	$ 199	$ 13,390
Stock-based compensation expense	—	—	2,013	—	—	2,013
Issuance of common stock upon vesting of restricted stock awards	543	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	—	(4)	(4)
Foreign currency translation adjustment	—	—	—	—	(55)	(55)
Net loss	—	—	—	(11,080)	—	(11,080)
Balances at March 31, 2024	6,421,627	$ 1	$ 257,926	$ (253,803)	$ 140	$ 4,264
Exercise of stock options	12,001	—	36	—	—	36
Stock-based compensation expense	—	—	1,951	—	—	1,951
Unrealized gain on available-for-sale securities	—	—	—	—	2	2
Foreign currency translation adjustment	—	—	—	—	28	28
Net loss	—	—	—	(6,785)	—	(6,785)
Balances at June 30, 2024	6,433,628	$ 1	$ 259,913	$ (260,588)	$ 170	$ (504)
Balances at December 31, 2022	3,737,921	1	196,252	(193,219)	203	3,237
Issuance of common stock	161,388	—	4,664	—	—	4,664
Stock-based compensation expense	—	—	2,223	—	—	2,223
Unrealized gain on available-for-sale securities	—	—	—	—	14	14
Foreign currency translation adjustment	—	—	—	—	4	4
Net loss	—	—	—	(11,770)	—	(11,770)
Balances at March 31, 2023	3,899,309	$ 1	$ 203,139	$ (204,989)	$ 221	$ (1,628)
Issuance of common stock	2,520,145	—	40,924	—	—	40,924
Issuance of equity-classified warrants	—	—	4,970	—	—	4,970
Stock-based compensation expense	—	—	2,451	—	—	2,451
Issuance of common stock upon vesting of restricted stock awards	544	—	—	—	—	—
Unrealized gain on available-for-sale securities	—	—	—	—	6	6
Foreign currency translation adjustment	—	—	—	—	(53)	(53)
Net loss	—	—	—	(25,143)	—	(25,143)
Balances at June 30, 2023	6,419,998	$ 1	$ 251,484	$ (230,132)	$ 174	$ 21,527

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (17,865)	$ (36,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	834	844
Non-cash lease expense	249	219
Commitment share expense	—	402
Issuance costs for common stock warrant liabilities	—	333
Loss on initial issuance of equity	—	14,840
Change in fair value of common stock warrant liabilities	(259)	383
Change in fair value of Clene Nanomedicine contingent earn-out liability	(75)	(1,110)
Change in fair value of Initial Stockholders contingent earn-out liability	(10)	(143)
Stock-based compensation expense	3,964	4,674
Accretion of debt discount	782	508
Non-cash interest income on marketable securities	(153)	—
Non-cash interest expense on notes payable	28	186
Changes in operating assets and liabilities:		
Accounts receivable	143	28
Inventory	—	(9)
Prepaid expenses and other current assets	(2,519)	1,733
Accounts payable	(438)	(2,168)
Accrued liabilities	2,207	235
Operating lease obligations	(326)	(281)
Net cash used in operating activities	(13,438)	(16,239)
Cash flows from investing activities:		
Purchases of marketable securities	(6,168)	—
Proceeds from maturities of marketable securities	12,500	5,000
Purchases of property and equipment	(13)	(239)
Net cash provided by investing activities	6,319	4,761
Cash flows from financing activities:		
Proceeds from exercise of stock options	36	—
Proceeds from issuance of common stock and warrants, net of offering costs	—	42,114
Payments of finance lease obligations	(27)	(46)
Proceeds from the issuance of notes payable	—	350
Net cash provided by financing activities	9	42,418
Effect of foreign exchange rate changes on cash and restricted cash	(29)	(29)
Net increase (decrease) in cash, cash equivalents and restricted cash	(7,139)	30,911
Cash, cash equivalents and restricted cash – beginning of period	28,879	18,390
Cash, cash equivalents and restricted cash – end of period	$ 21,740	$ 49,301
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	$ 21,682	$ 49,243
Restricted cash	58	58
Cash, cash equivalents and restricted cash	$ 21,740	$ 49,301
Supplemental disclosure of non-cash investing and financing activities:		
Accrued liability for debt modification fees	$ —	$ 200
Common stock warrant liability recorded upon debt modification	$ —	$ 692
Common stock warrant liability recorded upon public stock offering	$ —	$ 7,126
Supplemental cash flow information:		
Cash paid for interest expense	$ 1,716	$ 1,985

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 which 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 an exclusive license with 4Life Research LLC ("4Life"), an international supplier of health supplements, stockholder, and related party (see Note 15).

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

Going Concern

We incurred a loss from operations of $7.4 million and $10.3 million for the three months ended June 30, 2024 and 2023, respectively; and $16.6 million and $21.1 million for the six months ended June 30, 2024 and 2023, respectively. Our accumulated deficit was $260.6 million and $242.7 million as of June 30, 2024 and December 31, 2023, respectively. Our cash, cash equivalents, and marketable securities totaled $21.7 million and $35.0 million as of June 30, 2024 and December 31, 2023, respectively, and net cash used in operating activities was $13.4 million and $16.2 million for the six months ended June 30, 2024 and 2023, respectively.

We have incurred significant losses and negative cash flows from operations since our inception. We have not generated significant revenues since our inception, and we do not anticipate generating significant revenues unless we successfully complete development and obtain regulatory approval for commercialization of a drug candidate. We expect to incur additional losses in the future, particularly as we advance the development of our clinical-stage drug candidates, continue research and development of our preclinical drug candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our term loan with Avenue Venture Opportunities Fund, L.P. ("Avenue"), we are required to maintain unrestricted cash and cash equivalents of at least $5.0 million to avoid acceleration of the full balance of the loan (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, equity purchase agreement, and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. We have implemented cost-saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts and elimination of certain staff positions. We have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date the condensed consolidated financial statements 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., 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, 2024 and 2023 are unaudited.

Results of operations for the three and six months ended June 30, 2024 and 2023 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, 2024 and 2023 should be read in conjunction with the audited consolidated financial statements included in our Annual Report on Form 10-K.

Reverse Stock Split

Effective July 11, 2024 (the "Effective Date"), we filed a Certificate of Amendment to our Fourth Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, to effect a 1-for-20 reverse stock split (the "Reverse Stock Split") of our Common Stock. Beginning with the opening of trading on the Effective Date, our Common Stock began trading on Nasdaq on a split-adjusted basis under the same symbol, "CLNN." As a result of the Reverse Stock Split, every 20 shares of our Common Stock issued and outstanding were automatically combined and converted into 1 validly issued, fully paid and non-assessable share of Common Stock. In lieu of any fractional shares, stockholders received an amount in cash (without interest) equal to: (i) the number of shares of Common Stock held by such stockholder before the Reverse Stock Split that would otherwise have been exchanged for such fractional shares multiplied by (ii) the closing price of our Common Stock on Nasdaq on the trading day immediately preceding the Effective Date.

The Reverse Stock Split did not reduce the total number of authorized shares of Common Stock or preferred stock, par value $0.0001 per share ("Preferred Stock"), or change the par values of the Company's Common Stock or Preferred Stock. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of Common Stock were adjusted as a result of the Reverse Stock Split, in accordance with the terms of each such security. In addition, the number of shares reserved for issuance pursuant to our Amended 2020 Stock Plan was also appropriately adjusted. All historical share and per share data for the periods presented in these condensed consolidated financial statements, including for periods ending prior to July 11, 2024, has been adjusted to reflect the 1-for-20 Reverse Stock Split on a retroactive basis as if the Reverse Stock Split occurred as of the earliest period presented. As a result of the Reverse Stock Split, approximately $12,000 of par value was reclassified from Common Stock to Additional Paid-In Capital.

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 manufacturers 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 which 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.

Marketable Securities

Marketable securities are investments with original maturities of more than 90 days when purchased. We do not invest in securities with original maturities of more than one year. Marketable debt securities are considered available-for-sale, and are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income until realized. Realized gains and losses are included in other income (expense), net, on the basis of specific identification. The cost of marketable securities is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in other income (expense), net.

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, 2024, and $23,000 in raw material and $14,000 in finished goods as of December 31, 2023. 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

In connection with the Reverse Recapitalization, certain Clene Nanomedicine stockholders are entitled to receive additional shares of Common Stock (the "Clene Nanomedicine Contingent Earn-out") as follows: (i) 166,928 shares if (a) the volume-weighted average price ("VWAP") of our Common Stock equals or exceeds $300.00 (the "Milestone 1 Price") in any twenty trading days within a thirty trading day period within three years of the Reverse Recapitalization or (b) the change of control price equals or exceeds the Milestone 1 Price if a change of control transaction occurs within three years of the closing of the Reverse Recapitalization (the requirements in (a) and (b) collectively, "Milestone 1"); (ii) 125,200 shares if (a) the VWAP of our Common Stock equals or exceeds $400.00 (the "Milestone 2 Price") in any twenty trading days within a thirty trading day period within five years of the closing of the Reverse Recapitalization or (b) the change of control price equals or exceeds the Milestone 2 Price if a change of control transaction occurs within five years of the Reverse Recapitalization (the requirements in (a) and (b) collectively, "Milestone 2"). If Milestone 1 is not achieved but Milestone 2 is achieved, the Clene Nanomedicine stockholders will receive additional shares equal to Milestone 1. Tottenham's former officers, directors, sponsor, and public stockholders (the "Initial Stockholders") are entitled to receive earn-out shares (the "Initial Stockholders Contingent Earn-out," and collectively with the Clene Nanomedicine Contingent Earn-out, the "Contingent Earn-outs") as follows: (i) 18,750 shares upon the achievement of Milestone 1; and (ii) 18,750 shares upon achievement of Milestone 2. If Milestone 1 is not achieved but Milestone 2 is achieved, the Initial Stockholders will receive additional shares equal to Milestone 1.

In accordance with ASC 815, the Contingent Earn-outs are not indexed to our own stock and therefore were accounted for as a liability at the Reverse Recapitalization date and are subsequently remeasured to fair value at each reporting date with changes recorded as a component of other income (expense), net.

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 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 of $1.7 million and $0.1 million during the three months ended June 30, 2024 and 2023, respectively; and $2.0 million and $0.1 million during the six months ended June 30, 2024 and 2023, respectively.

In October 2023 we were awarded a grant ("the NIH Grant") in collaboration with Columbia University, the prime awardee, and Synapticure, a neurology specialty health clinic, from the National Institute 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. These subawards are awarded annually and subaward funds are paid to us as reimbursement for cash spent by us to support the ACT-EAP. The first subaward was granted on April 9, 2024 for $7.4 million and may be paid to us for reimbursements submitted during the period from September 25, 2023 to August 31, 2024.

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' equity (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' equity (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' equity (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 and our unrealized gain (loss) on available-for-sale securities.

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. Effective in the fourth quarter of 2023, we revised our internal reporting processes to better align with our strategic priorities due to the immateriality of our dietary supplement operations. As a result and in accordance with ASC 280, we determined that the Company is a single operating and reportable segment. Our chief executive officer is the CODM and allocates resources and assesses performance at a consolidated level. Prior to the fourth quarter of 2023, we operated as two operating and reportable segments related to our development and commercialization of drugs and dietary supplements. The change did not require any prior period information to be recast.

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. 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. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertainty in income taxes recognized in the condensed consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the condensed consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, which are considered appropriate as well as the related net interest and penalties.

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. 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 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 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 generally grant stock options with a four-year requisite service period. Certain stock options may vest based upon performance conditions instead of service conditions, such as the achievement of regulatory milestones or financial performance measures. 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. We elect to account for forfeitures as they occur, rather than estimating expected forfeitures. We determine the fair value of each share of Common Stock underlying stock-based awards using a Black-Scholes option pricing model based on the closing price of our Common Stock as reported by Nasdaq on the date of grant. The fair value of stock awards with market conditions are determined using a Monte Carlo valuation model.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 requires, among other things, that public entities with a single reportable segment provide all the disclosures required by ASC 280 and ASU 2023-07, and that public entities provide all annual disclosures about a reportable segment's profit or loss and assets currently required in interim periods. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. We are currently evaluating the impact of ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 requires, among other things, that public entities on an annual basis disclose specific categories of the tax rate reconciliation, provide additional information for reconciling items that meet a quantitative threshold, and disclose income taxes paid disaggregated by jurisdiction. The guidance is effective for annual periods beginning after December 15, 2024. We are currently evaluating the impact of ASU 2023-09.

Note 3. Cash, Cash Equivalents, and Marketable Securities

Available-for-Sale Securities

Available-for-sale securities as of June 30, 2024 were as follows:

	June 30, 2024			
(in thousands)	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash equivalents (contractual maturity within 90 days):				
U.S. Treasury securities	$ 10,955	$ —	$ (1)	$ 10,954
Money market funds	3,341	—	—	3,341
Total cash equivalents	14,296	—	(1)	14,295
Cash	7,387	—	—	7,387
Total cash and cash equivalents	$ 21,683	$ —	$ (1)	$ 21,682

Available-for-sale securities as of December 31, 2023 were as follows:

(in thousands)	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents (contractual maturity within 90 days):				
U.S. Treasury securities	$ 19,883	$ 1	$ —	$ 19,884
Money market funds	5,113	—	—	5,113
Total cash equivalents	24,996	1	—	24,997
Cash	3,824	—	—	3,824
Total cash and cash equivalents	$ 28,820	$ 1	$ —	$ 28,821
Marketable securities (contractual maturity greater than 90 days but less than 1 year):				
U.S. Treasury securities	$ 6,179	$ —	$ —	$ 6,179
Total marketable securities	$ 6,179	$ —	$ —	$ 6,179

We had no realized gains or losses from the sale of available-for-sale securities during the three and six months ended June 30, 2024 and 2023. As of June 30, 2024 and December 31, 2023, we did not have any allowance for credit losses or impairments of available-for-sale securities.

Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of June 30, 2024 and December 31, 2023 were as follows:

(in thousands)	June 30, 2024	December 31, 2023
Prepaid clinical and CRO expenses	$ 2,375	$ —
Metals to be used in research and development	1,688	1,909
Research and development tax credits receivable	1,217	1,195
Other	911	568
Total prepaid expenses and other current assets	$ 6,191	$ 3,672

Note 5. Property and Equipment, Net

Property and equipment, net, as of June 30, 2024 and December 31, 2023 were as follows:

(in thousands)	June 30, 2024	December 31, 2023
Lab equipment	$ 4,078	$ 4,092
Office equipment	178	178
Computer software	460	459
Leasehold improvements	9,983	9,983
Construction in progress	1,450	1,438
	16,149	16,150
Less accumulated depreciation	(7,707)	(6,887)
Total property and equipment, net	$ 8,442	$ 9,263

Depreciation expense recorded in research and development expense and general and administrative expense during the three and six months ended June 30, 2024 and 2023 was as follows:

(in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
General and administrative	$ 67	$ 67	$ 133	$ 134
Research and development	347	375	701	710
Total depreciation expense	$ 414	$ 442	$ 834	$ 844

Note 6. Accrued Liabilities

Accrued liabilities as of June 30, 2024 and December 31, 2023 were as follows:

(in thousands)	June 30, 2024	December 31, 2023
Accrued compensation and benefits	$ 3,068	$ 2,120
Deferred grants	2,008	438
Accrued CRO and clinical fees	809	481
Other	42	681
Total accrued liabilities	$ 5,927	$ 3,720

Note 7. Leases

We lease laboratory and office space and certain laboratory equipment under non-cancellable operating and finance 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.

Operating Leases

Operating leases primarily consist of real estate leases for office and laboratory space. We have three real estate leases: (i) a laboratory and manufacturing facility which 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 which commenced in February 2022 with a seven-year term and an option to extend for two five-year periods, and (iii) our corporate office which commenced a renewed term in September 2022 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, 2024 and December 31, 2023, our operating lease obligations had a weighted-average discount rate of 9.6% and 9.6%, respectively, and a weighted-average remaining term of 5.9 years and 6.4 years, respectively.

Finance Leases

We did not have any finance lease obligations as of June 30, 2024. Assets recorded under finance lease obligations and included within property and equipment as of December 31, 2023 were as follows:

(in thousands)	December 31, 2023
Lab equipment	$ 636
Less accumulated depreciation	(449)
Net	$ 187

As of December 31, 2023, our finance lease obligations had a weighted-average interest rate of 11.0% and a weighted-average remaining term of 0.4 years.

Maturity Analysis of Lease Obligations

The maturity analysis of our operating lease obligations as of June 30, 2024 was as follows:

(in thousands)	Operating Leases
2024 (remainder)	$ 495
2025	1,208
2026	1,236
2027	1,132
2028	1,093
2029	649
Thereafter	1,045
Total minimum lease payments	6,858
Less amount representing interest/discounting	(1,705)
Present value of minimum lease payments	5,153
Less lease obligations, current portion	(623)
Lease obligations, net of current portion	$ 4,530

Components of Lease Cost

The components of finance and operating lease costs for the three and six months ended June 30, 2024 and 2023 were as follows:

(in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Finance lease costs:				
Amortization	$ 18	$ 21	$ 45	$ 41
Interest on lease liabilities	—	3	—	9
Operating lease costs	255	251	509	504
Short-term lease costs	2	2	2	2
Variable lease costs	76	72	129	122
Total lease costs	$ 351	$ 349	$ 685	$ 678

Supplemental Cash Flow Information

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Operating cash flows from operating leases	$ (640)	$ (628)
Operating cash flows from finance leases	$ —	$ (9)
Financing cash flows from finance leases	$ (27)	$ (46)

Note 8. Notes Payable and Convertible Notes Payable

Our notes payable and convertible notes payable as of June 30, 2024 and December 31, 2023 was as follows:

(in thousands, except interest rates)	Stated Interest Rate	June 30, 2024	December 31, 2023
Notes payable			
Advance Cecil, Inc. (commenced April 2019)	8.00%	$ 142	$ 138
Maryland DHCD (commenced February 2019)	8.00%	714	694
Maryland DHCD (commenced May 2022)	6.00%	1,083	1,083
Avenue Venture Opportunities Fund, L.P. (commenced May 2021)	15.10%	20,000	15,000
		21,939	16,915
Unamortized premium (discount) and debt issuance costs		259	(394)
Less notes payable, current portion, net of unamortized discount and debt issuance costs		(20,453)	(14,627)
Notes payable, net of current portion		$ 1,745	$ 1,894
Convertible notes payable			
Avenue Venture Opportunities Fund, L.P. (commenced May 2021)	15.10%	$ —	$ 5,000
Maryland DHCD (commenced December 2022)	6.00%	5,312	5,308
		5,312	10,308
Unamortized discount and debt issuance costs		(44)	(174)
Less convertible notes payable, current portion, net of unamortized discount and debt issuance costs		—	(4,876)
Convertible notes payable, net of current portion		$ 5,268	$ 5,258

Maryland Loans

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 established "Phantom Shares" based on 5,995 shares of Common Stock. 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) the Phantom Shares multiplied by the closing price of our Common Stock on Nasdaq on the trading day prior to the maturity date. As of June 30, 2024 and December 31, 2023, the 2019 MD Loan was recorded at principal plus accrued interest as it was greater than the value of the Phantom Shares. We recognized interest expense of $10,000 and $10,000 during the three months ended June 30, 2024 and 2023, respectively; and $20,000 and $20,000 during the six months ended June 30, 2024 and 2023, respectively.

In April 2019, we entered into a term loan agreement (the "2019 Cecil Loan") with Advance Cecil Inc., a non-stock corporation formed under the laws of the State of Maryland, for $0.1 million bearing simple interest at an annual rate of 8.00%. The 2019 Cecil Loan established "Phantom Shares" based on 1,199 shares of Common Stock. 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) the Phantom Shares multiplied by the closing price of our Common Stock on Nasdaq on the trading day prior to the maturity date. As of June 30, 2024 and December 31, 2023, the 2019 Cecil Loan was recorded at principal plus accrued interest as it was greater than the value of the Phantom Shares. We recognized interest expense of $2,000 and $2,000 during the three months ended June 30, 2024 and 2023, respectively; and $4,000 and $4,000 during the six months ended June 30, 2024 and 2023, respectively.

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"). As of June 30, 2024, we had drawn $1.0 million with the remaining balance available for future equipment purchases expiring on May 17, 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, 2024 and December 31, 2023, 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. Under an agreement between DHCD and Avenue, an existing secured creditor of the Company, DHCD was granted a first priority lien on the Assets as collateral. We recognized interest expense of $16,000 and $16,000 during the three months ended June 30, 2024 and 2023, respectively; and $31,000 and $28,000 during the six months ended June 30, 2024 and 2023, respectively.

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, 2024 and December 31, 2023, 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. We recorded debt issuance costs of $0.1 million as a debt discount. At any time after December 8, 2023, DHCD may, in its sole discretion, convert up to $5.0 million of principal into Common Stock in increments of $1.0 million, at a price equal to the greater of: (i) 97% of the 30-day trailing 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. During the three months ended June 30, 2024 and 2023, we recognized (i) total interest expense of $0.1 million and $0.1 million, respectively; (ii) coupon interest expense of $0.1 million and $0.1 million, respectively; and (iii) amortization of debt issuance costs of $3,000 and $0, respectively; and the effective interest rate was 5.99% and 5.91%, respectively. During the six months ended June 30, 2024 and 2023, we recognized (i) total interest expense of $0.2 million and $0.2 million, respectively; (ii) coupon interest expense of $0.2 million and $0.2 million, respectively; and (iii) amortization of debt issuance costs of $5,000 and ($2,000), respectively; and the effective interest rate was 5.99% and 5.91%, respectively.

Avenue Loan

In May 2021, we entered into a term loan agreement (the "2021 Avenue Loan") with Avenue for up to $30.0 million, bearing interest at a variable rate equal to (i) the greater of (a) the prime rate or (b) 3.25%, plus (ii) 6.60%. As of June 30, 2024 and December 31, 2023, the interest rate was 15.10% and 14.10%, respectively. We borrowed $15.0 million in May 2021 plus $5.0 million in September 2021 ("Tranche 1"), and the remaining $10.0 million ("Tranche 2") was not drawn and expired. We incurred $0.8 million of debt issuance costs of which $47,000 related to liability-classified warrants was expensed immediately and the remainder was recorded as a debt discount. Payments were interest-only for the first 12 months and the interest-only period was extended for (i) 12 months due to our achievement of certain clinical trial milestones, plus (ii) an additional 12 months (through June 30, 2024), pursuant to an amendment in June 2023 (the "Second Amendment"), due to our receipt of at least $35.0 million from the sale and issuance of Common Stock in a public offering in June 2023 ("Equity Milestone 1"). Following the interest-only period, beginning July 1, 2024 we are required to make equal monthly installments of principal plus interest at the variable rate then in effect until the maturity date of December 1, 2024. Additionally, a payment of 4.25% of the funded principal, equal to $0.9 million (the "Final Payment"), is due at maturity, which we recorded as a debt premium.

Avenue had the right to convert up to $5.0 million of principal into Common Stock (the "Avenue Conversion Feature"), which expired on May 21, 2024 and was not exercised. The Final Payment and Avenue Conversion Feature did not meet the requirements for derivative accounting. As of June 30, 2024 and December 31, 2023, unamortized debt discount and issuance costs related to the convertible note were $0 and $0.1 million, respectively. For the convertible note during the three months ended June 30, 2024 and 2023, we recognized (i) total interest expense of $0.2 million and $0.3 million, respectively; (ii) coupon interest expense of $0.1 million and $0.2 million, respectively; and (iii) amortization of debt discount and issuance costs of $0.1 million and $0.1 million, respectively; and the effective interest rate was 22.79% and 22.55%, respectively. During the six months ended June 30, 2024 and 2023, we recognized (i) total interest expense of $0.4 million and $0.5 million, respectively; (ii) coupon interest expense of $0.3 million and $0.4 million, respectively; and (iii) amortization of debt discount and issuance costs of $0.1 million and $0.1 million, respectively; and the effective interest rate was 22.79% and 22.55%, respectively.

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; limitations on our ability to pay dividends; and we are required to maintain unrestricted cash and cash equivalents of at least $5.0 million. We are not in violation of any covenants. Avenue has the ability to immediately accelerate all obligations under the 2021 Avenue Loan upon the occurrence of certain events of default or material adverse effects. The 2021 Avenue Loan is collateralized by substantially all our assets other than intellectual property, including our capital stock and the capital stock of our subsidiaries, in which Avenue is granted a continuing security interest. We recognized interest expense of $1.2 million and $1.0 million during the three months ended June 30, 2024 and 2023, respectively; and $2.3 million and $2.0 million during the six months ended June 30, 2024 and 2023, respectively.

At the inception of the 2021 Avenue Loan, we issued a warrant to Avenue to purchase Common Stock (the "Original Avenue Warrant"). A portion of the net proceeds at issuance of the 2021 Avenue Loan were allocated to the Original Avenue Warrant in an amount equal to its fair value of $1.5 million and were recorded as a debt discount. Pursuant to the Second Amendment, the Original Avenue Warrant was cancelled and a new warrant to purchase 150,000 shares of Common Stock at $16.00 per share was issued (the "New Avenue Warrant"). Avenue may exercise the New Avenue Warrant for cash or on a net or "cashless" basis. In the event of a change of control of the Company, the New Avenue Warrant shall be automatically exchanged for the number of shares of Common Stock which remain exercisable thereunder immediately prior to the change of control transaction, for no payment or consideration from Avenue for such shares, and the New Avenue Warrant shall be terminated. At issuance, the New Avenue Warrant was recorded as a liability and debt discount in amount equal to its fair value of $0.7 million. The Second Amendment, including the revised terms, cancellation of the Original Avenue Warrant, and issuance of the New Avenue Warrant was accounted for as a debt modification.

Debt Maturities

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

(in thousands)	2019 MD Loan	2019 Cecil Loan	2021 Avenue Loan	2022 MD Loan	2022 DHCD Loan
2024 (remainder)	$ —	$ —	$ 20,000	$ —	$ —
2025	—	—	—	347	—
2026	—	—	—	369	—
2027	—	—	—	317	—
2028	—	—	—	—	5,000
2029	—	—	—	—	—
Thereafter	500	100	—	—	—
Total debt principal payments	500	100	20,000	1,033	5,000
Accrued and unpaid interest	214	42	—	50	312
Unamortized premium (discount) and debt issuance costs	—	—	277	(18)	(44)
Future debt payments, net	$ 714	$ 142	$ 20,277	$ 1,065	$ 5,268

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, 2024 and December 31, 2023, we had commitments under various agreements for capital expenditures totaling $0.2 million and $0.4 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 the following grants from the National Multiple Sclerosis Society ("NMSS"): (i) $0.3 million in September 2019 (the "2019 Grant") to fund biomarker research related our VISIONARY-MS Phase 2 clinical trial, and (ii) $0.7 million in May 2023 (the "2023 Grant") to fund Cohort 2 of our REPAIR-MS clinical trial. Pursuant to the grant agreements, if we make future commercial sales of CNM-Au8 for the treatment of MS, we will repay: (i) 50% of the grants upon the first commercial product 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 equal to 450% of the grants if all milestones are achieved. If NMSS has not yet received repayments equal in the aggregate to 300% of the 2019 Grant or 150% of the 2023 Grant, then upon the closing of any of the following events we will repay 300% of the 2019 Grant, equal to $1.0 million, or 150% of the 2023 Grant, equal to $1.0 million, less any amounts previously paid by us: (i) sale of all or substantially all of our assets and business, (ii) a public offering that occurs more than twelve months after completion of the applicable research, (iii) sale of any portion of our assets and business including CNM-Au8 for the treatment of MS, (iv) exclusive licensing of our intellectual property claiming CNM-Au8 for the treatment of MS, (v) a collaboration with a third-party to develop CNM-Au8 for the treatment of MS (for the 2019 Grant only), or (vi) licensing of our commercialization rights to CNM-Au8 for the treatment of MS (for the 2023 Grant only). As of June 30, 2024, we have not met any of the above milestones and the applicable research has not been completed. We accounted for these contingencies in accordance with ASC 450, *Contingencies*. Management has assessed the likelihood of each contingent event as less than probable and therefore no contingent liability is recognized. Management's 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 Management's 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, 2024 and 2023 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2024	2023	2024	2023
United States	$ (6,741)	$ (24,856)	$ (17,780)	$ (36,402)
Foreign	(44)	(287)	(85)	(511)
Net loss before income taxes	$ (6,785)	$ (25,143)	$ (17,865)	$ (36,913)

We are subject to taxation in the U.S., Australia, Netherlands, and various state jurisdictions. Our tax returns from 2017 to present are subject to examination by the U.S. and state authorities due to the carry forward of unutilized net operating losses and research and development credits. There are currently 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 $0.1 million and $0.1 million during the three months ended June 30, 2024 and 2023, respectively; and $0.1 million and $0.1 million during the six months ended June 30, 2024 and 2023, 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, 2024, 255,876 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 and 2,420,000 shares of Common Stock are reserved for issuance thereunder. As of June 30, 2024, a total of 1,624,256 stock options and other stock awards had been granted under the 2020 Plan, and 795,744 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, 2024 and 2023 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
General and administrative	$ 1,048	$ 1,327	$ 2,184	$ 2,577
Research and development	903	1,124	1,780	2,097
Total stock-based compensation expense	$ 1,951	$ 2,451	$ 3,964	$ 4,674

Stock-based compensation expense by award type during the three and six months ended June 30, 2024 and 2023 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Stock options	$ 1,951	$ 2,438	$ 3,953	$ 4,660
Stock awards	—	13	11	14
Total stock-based compensation expense	$ 1,951	$ 2,451	$ 3,964	$ 4,674

Stock Options

Outstanding stock options and related activity during the six months ended June 30, 2024 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, 2023	1,092,343	$ 45.20	7.28	$ 302
Granted	753,724	7.44	9.94	—
Exercised	(12,001)	3.00	—	49
Forfeited	(8,637)	91.99	—	—
Outstanding – June 30, 2024	1,825,429	$ 29.71	8.12	$ 375
Vested and exercisable – June 30, 2024	726,146	$ 48.66	6.14	$ 375
Vested, exercisable or expected to vest – June 30, 2024	1,825,429	$ 29.71	8.12	$ 375

As of June 30, 2024 and December 31, 2023, we had approximately $11.8 million and $13.7 million, respectively, of unrecognized stock-based compensation costs related to non-vested stock options which is expected to be recognized over a weighted-average period of 1.99 years and 2.10 years, respectively.

The weighted-average grant-date fair value of stock options granted during the six months ended June 30, 2024 and 2023 was $6.51 and $15.40, respectively. The assumptions used to calculate the fair value of stock options granted during the six months ended June 30, 2024 and 2023 were as follows:

	Six Months Ended June 30,	
	2024	**2023**
Expected stock price volatility	97.78% –110.82%	96.22% –103.24%
Risk-free interest rate	4.04% –4.58%	3.26% –4.17%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 –10.00	5.00 –6.43

Stock Awards

Stock awards include rights to restricted stock awards with market-based vesting conditions and restricted stock units with service-based vesting conditions. Outstanding stock awards and related activity during the six months ended June 30, 2024 was as follows:

	Number of Stock Awards	Weighted Average Grant Date Fair Value
Unvested balance – December 31, 2023	38,943	$ 194.41
Converted to shares of Common Stock upon vesting	(543)	23.00
Forfeited	(37)	196.89
Unvested balance – June 30, 2024	38,363	$ 196.84

As of June 30, 2024, we had no unrecognized stock-based compensation cost related to non-vested stock awards. As of December 31, 2023, we had approximately $11,000 of unrecognized stock-based compensation costs related to non-vested stock awards expected to be recognized over a weighted-average period of 0.23 years.

Note 12. Fair Value

Cash, cash equivalents, and marketable securities 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, 2024 is as follows:

	June 30, 2024			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
U.S. Treasury securities	$ —	$ 10,954	$ —	$ 10,954
Money market funds	3,341	—	—	3,341
Common stock warrant liabilities	—	—	1,222	1,222
Clene Nanomedicine contingent earn-out liability	—	—	—	—
Initial Stockholders contingent earn-out liability	—	—	—	—

The fair value hierarchy for financial instruments measured at fair value on a recurring basis as of December 31, 2023 is as follows:

	December 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
U.S. Treasury securities	$ —	$ 19,884	$ —	$ 19,884
Money market funds	5,113	—	—	5,113
Marketable securities:				
U.S. Treasury securities	—	6,179	—	6,179
Common stock warrant liabilities	—	—	1,481	1,481
Clene Nanomedicine contingent earn-out liability	—	—	75	75
Initial Stockholders contingent earn-out liability	—	—	10	10

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, 2024 were as follows:

(in thousands)	Common Stock Warrant Liabilities	Clene Nanomedicine Contingent Earn-out	Initial Stockholders Contingent Earn-out
Balance – December 31, 2023	$ 1,481	$ 75	$ 10
Change in fair value	(259)	(75)	(10)
Balance – June 30, 2024	$ 1,222	$ —	$ —

Changes in the fair value of our Level 3 financial instruments during the six months ended June 30, 2023 were as follows:

(in thousands)	Common Stock Warrant Liabilities	Clene Nanomedicine Contingent Earn-out	Initial Stockholders Contingent Earn-out
Balance – December 31, 2022	$ —	$ 2,264	$ 291
Initial fair value of instruments	7,818	—	—
Change in fair value	383	(1,110)	(143)
Balance – June 30, 2023	$ 8,201	$ 1,154	$ 148

Valuation of Notes Payable and Convertible Notes Payable

The 2019 MD Loan and the 2019 Cecil Loan are carried at the greater of principal plus accrued interest or the value of the Phantom Shares (see Note 8), which approximates fair value. The 2021 Avenue Loan, the 2022 MD Loan, and the 2022 DHCD Loan are carried at amortized cost, which approximates fair value due to our credit risk and market interest rates. Our notes payable and convertible notes payable are categorized within Level 3 of the fair value hierarchy.

Valuation of the Common Stock Warrant Liabilities

The New Avenue Warrant 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 the following events: (i) settlement of the instrument upon a change of control transaction, (ii) dissolution of the Company, or (iii) another outcome outside of (i)-(ii). 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 inputs to the Black-Scholes option pricing model were as follows:

	June 30, 2024	December 31, 2023
Expected stock price volatility	79.00% –99.80%	105.00% –110.00%
Risk-free interest rate	4.40% –5.40%	3.88% –5.03%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	0.42 –4.00	0.75 –4.50
Probability of change of control	10.00%	25.00%
Probability of dissolution	55.00%	50.00%
Probability of other outcome	35.00%	25.00%

The Tranche A Warrants are classified as a liability and carried at fair value (the Tranche B Warrants qualified for equity classification at issuance). We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of the following events: (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) another outcome outside of (i)-(iii). 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 inputs to the Black-Scholes option pricing model were as follows:

	June 30, 2024	December 31, 2023
Expected stock price volatility	91.90% –103.70%	100.00% –110.00%
Risk-free interest rate	4.70% –5.20%	4.13% –4.74%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	0.75 –1.96	1.08 –2.46
Probability of NDA acceptance	30.00%	20.00%
Probability of fundamental transaction	10.00%	25.00%
Probability of dissolution	55.00%	50.00%
Probability of other outcome	5.00%	5.00%

Valuation of the Contingent Earn-Out Liabilities

The Contingent Earn-outs are carried at fair value, determined using a Monte Carlo valuation model in order to simulate the future path of our stock price over the earn-out periods. The carrying amount of the liabilities may fluctuate significantly and actual amounts paid may be materially different from the liabilities' estimated value. The unobservable inputs to the Monte Carlo valuation model were as follows:

	June 30, 2024	December 31, 2023
Expected stock price volatility	90.00%	115.00%
Risk-free interest rate	4.90%	4.20%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	1.50	2.00

Note 13. Capital Stock

As of June 30, 2024 and December 31, 2023, our amended and restated certificate of incorporation authorized us to issue 600,000,000 and 300,000,000 shares of Common Stock par value $0.0001 per share, respectively; and 1,000,000 shares of Preferred Stock, par value $0.0001 per share. As of June 30, 2024 and December 31, 2023, we had 6,433,628 and 6,421,084 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 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 Preferred Stock. No distributions shall be made with respect to Common Stock until all declared dividends to Preferred Stock have been paid or set aside for payment. Common Stock is not redeemable at the option of the holder.

Common Stock Warrants

As of June 30, 2024 and December 31, 2023, outstanding warrants to purchase shares of Common Stock were as follows:

Date Exercisable	Exercise Price	Expiration		Classification	Number of Shares Issuable June 30, 2024	Number of Shares Issuable December 31, 2023
December 2020	$ 230.00	December 2025	(1)	Equity	120,375	120,375
December 2020	$ 230.00	December 2025	(2)	Equity	1,229	1,229
June 2023	$ 16.00	June 2028	(3)	Liability	150,000	150,000
June 2023	$ 22.00	June 2026	(4)	Liability	2,500,000	2,500,000
June 2023	$ 30.00	June 2030	(5)	Equity	2,500,000	2,500,000
Total					5,271,604	5,271,604

(1) Represents 120,375 shares of Common Stock underlying warrants to purchase one-fortieth (1/40) of one share of Common Stock, issued during Tottenham's initial public offering. We may redeem the outstanding warrants at $0.01 per warrant if the last sales price of our Common Stock equals or exceeds $330.00 per share for any 20 trading days within a 30-trading day period. As of June 30, 2024 and December 31, 2023, no warrants had been exercised.

(2) Represents 1,229 shares of Common Stock underlying warrants to purchase one-fortieth (1/40) of one share of Common Stock, issued to the financial advisor and lead underwriter of Tottenham's initial public offering upon their exercise of a unit purchase option in July 2021. As of June 30, 2024 and December 31, 2023, no warrants had been exercised.

(3) Represents 150,000 shares of Common Stock underlying the New Avenue Warrant, issued pursuant to the Second Amendment (see Note 8). As of June 30, 2024 and December 31, 2023, the warrant had not been exercised.

(4) Represents 2,500,000 shares of Common Stock underlying the Tranche A Warrants to purchase one share of Common Stock, issued in our June 2023 public equity offering. As of June 30, 2024 and December 31, 2023, no warrants had been exercised.

(5) Represents 2,500,000 shares of Common Stock underlying the Tranche B Warrants to purchase one share of Common Stock, issued in our June 2023 public equity offering. As of June 30, 2024 and December 31, 2023, no warrants had been exercised.

Public Offerings

In June 2023, we sold 2,500,000 units at a sale price of $16.00 per unit pursuant to an underwriting agreement with Canaccord Genuity LLC ("Canaccord") as underwriter. Each unit consisted of (i) one share of Common Stock, (ii) one warrant to purchase one share of Common Stock at an exercise price of $22.00 per share (the "Tranche A Warrants"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $30.00 per share (the "Tranche B Warrants"). The aggregate gross proceeds were $40.0 million, excluding the proceeds, if any, from the exercise of the Tranche A and Tranche B Warrants. We cannot predict when or if the Tranche A or Tranche B Warrants will be exercised, and it is possible they may expire and/or never be exercised. We paid underwriting discounts and commissions of $2.4 million and offering expenses of $0.2 million. The Tranche A Warrants were exercisable immediately and will expire on the earlier of (i) sixty (60) days following the date of our public announcement that the filing of an NDA for CNM-Au8 has been accepted by the FDA, or (ii) June 16, 2026. The Tranche B Warrants were exercisable immediately and will expire on the earlier of (i) sixty (60) days following the date of our public announcement that an NDA for CNM-Au8 has been approved by the FDA, or (ii) June 16, 2030. If we enter into or become party to a fundamental transaction (which generally includes a merger of the Company with or into another entity; the sale, lease, license, or transfer of all or substantially all of our assets; tender or exchange offers; or reclassification, reorganization, or recapitalization of our Common Stock), then (i) we or our successor entity shall purchase all outstanding Tranche A Warrants by paying the holders cash in an amount equal to the Black-Scholes value of the remaining unexercised portion of each Tranche A Warrant, and (ii) upon any subsequent exercise of a Tranche B Warrant, the holder shall be entitled to receive, at the option of the holder, the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such fundamental transaction by a holder of the number of shares of Common Stock for which the warrant is exercisable immediately prior to such fundamental transaction. The offering was made pursuant to our registration statement on Form S-3 (file number 333-264299), which was declared effective by the SEC on April 26, 2022, a related registration statement pursuant to Rule 462(b) (file number 333-272692), filed with the SEC and effective on June 16, 2023, and our prospectus supplement relating to the offering. The total fair value of the Tranche A Warrants, Tranche B Warrants, and shares of Common Stock sold in the offering exceeded the offering proceeds by $14.8 million, therefore pursuant to ASC 815, this amount was recognized as a loss on the initial issuance of equity in the condensed consolidated statements of operations and comprehensive loss during the year ended December 31, 2023. The underwriting discounts and commissions and underwriting expenses were allocated to the shares of Common Stock, Tranche A Warrants, and Tranche B Warrants sold in the offering based on their relative fair values, with the amount allocated to the liability-classified Tranche A Warrants recorded as an expense in the condensed consolidated statements of operations and comprehensive loss, and the amounts allocated to the shares of Common Stock and Tranche B Warrants as a reduction to their initial carrying values.

Common Stock Sales Agreement

In April 2022, we entered into an Equity Distribution Agreement, which we amended in December 2022 (the "ATM Agreement"). Canaccord acts as placement agent and we may offer and sell shares of Common Stock from time to time through Canaccord. The issuance and sale of Common Stock by us under the ATM Agreement is made pursuant to our registration statement on Form S-3 (file number 333-264299), which was declared effective by the Securities and Exchange Commission on April 26, 2022. We subsequently terminated and filed a new prospectus supplement relating to the offering, which was most recently amended on May 8, 2024 for the future offer and sale of Common Stock having an aggregate offering price of up to $12.3 million.

Pursuant to the ATM Agreement, Canaccord is not required to sell any specific number or dollar amount of 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. Canaccord is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from each sale of Common Stock, if any. We did not sell any shares during the three and six months ended June 30, 2024. During the three and six months ended June 30, 2023, we sold 0 and 144,755 shares of Common Stock, respectively; generated gross proceeds of $0 and $4.5 million, respectively; and paid commissions of $0 and $0.1 million, respectively.

Common Stock Purchase Agreement

On March 3, 2023, we entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase up to $25.0 million of shares of Common Stock at our sole discretion, from time to time over a 36-month period commencing on March 7, 2023. The issuance and sale of Common Stock under the Purchase Agreement was made pursuant to our registration statement on Form S-3 (file number 333-264299), which was declared effective by the SEC on April 26, 2022. On June 16, 2023, we suspended and terminated the prospectus supplement (the "Purchase Agreement Prospectus Supplement") related to the offering with respect to the unsold shares of Common Stock issuable pursuant to the Purchase Agreement. We will not make any further sales of our securities pursuant to the Purchase Agreement, unless and until a new prospectus supplement is filed. Other than the termination of the Purchase Agreement Prospectus Supplement and offering with respect to future sales by us, the Purchase Agreement remains in full force and effect.

Pursuant to the Purchase Agreement, we may direct Lincoln Park to purchase up to 3,750 shares of Common Stock (a "Regular Purchase"), which may be increased up to (i) 5,000 shares if the closing price of our Common Stock is not below $20.00, (ii) 7,500 shares if the closing price of our Common Stock is not below $40.00, and (iii) 10,000 shares if the closing price of our Common Stock is not below $80.00. The purchase price for a Regular Purchase is based on the market price of our Common Stock at the time of sale. We may sell shares in excess of a Regular Purchase (an "Accelerated Purchase") on any day on which we have directed Lincoln Park to purchase the maximum amount allowed for such Regular Purchase, up to the lesser of (i) 300% of the number of shares purchased pursuant to such prior business day Regular Purchase or (ii) 30% of the aggregate shares of our Common Stock traded on Nasdaq on the trading day immediately following the purchase date for such Regular Purchase (subject to certain volume and market price limitations). Additionally, we may sell shares in excess of an Accelerated Purchase (an "Additional Accelerated Purchase") on any day on which we have directed Lincoln Park to purchase the maximum amount allowed for such Accelerated Purchase, up to the lesser of (i) 300% of the number of shares purchased pursuant to such prior business day Regular Purchase or (ii) 30% of the aggregate shares of our Common Stock traded on Nasdaq during a certain period on the date of the Additional Accelerated Purchase (subject to certain volume and market price limitations). The purchase price for Accelerated Purchases and Additional Accelerated Purchases is equal to 97% of the lesser of (i) the VWAP of our Common Stock on Nasdaq during certain periods on the date of the Accelerated Purchase or Additional Accelerated Purchase or (ii) the closing price of our Common Stock on the date of the Accelerate Purchase or Additional Accelerated Purchase.

On the date of the Purchase Agreement, we issued 16,633 shares of Common Stock (the "Initial Commitment Shares") to Lincoln Park as an initial fee for its commitment under the Purchase Agreement. We recorded the fair value of the Initial Commitment Shares on the date of issuance in other income (expense), net. We may further issue up to 8,317 additional shares of Common Stock (the "Additional Commitment Shares," and, together with the Initial Commitment Shares, the "Commitment Shares") on a pro rata basis upon each purchase by Lincoln Park under the Purchase Agreement. Under applicable Nasdaq listing rules, the total number of shares of Common Stock that we may sell to Lincoln Park is limited to 765,506 shares (including the Commitment Shares), representing 19.99% of the outstanding shares of our Common Stock immediately prior to the execution of the Purchase Agreement, unless we (i) first obtain stockholder approval in accordance with applicable Nasdaq listing rules or (ii) the average price paid by Lincoln Park for all shares of Common Stock issued by us under the Purchase Agreement is equal to or greater than $24.8080. The Purchase Agreement prohibits us from directing Lincoln Park to purchase any shares of Common Stock that would result in Lincoln Park having beneficial ownership of greater than 4.99% of our outstanding Common Stock, which Lincoln Park may, in its sole discretion, increase up to 9.99% of our outstanding Common Stock by delivering written notice thereof to us, which shall not be effective until the 61st day after such written notice is delivered to us. We may terminate the Purchase Agreement at any time, for any reason and without any payment or liability to us, by giving Lincoln Park a termination notice with effect one business date after the notice has been received by Lincoln Park.

We evaluated the Purchase Agreement under ASC 815-40 *Derivatives and Hedging—Contracts on an Entity's Own Equity* as it represents the right to require Lincoln Park to purchase shares of Common Stock in the future, similar to a put option. We concluded it represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. We analyzed the terms of the contract and concluded the derivative instrument has no value as of June 30, 2024 and December 31, 2023. We did not sell any shares during the during the three and six months ended June 30, 2024. During the three and six months ended June 30, 2023, we sold 20,000 shares of Common Stock under the Purchase Agreement, issued 145 Additional Commitment Shares, and generated proceeds of $0.4 million.

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, 2024 and 2023 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except share and per share data)	**2024**	**2023**	**2024**	**2023**
Numerator:				
Net loss attributable to common stockholders	$ (6,785)	$ (25,143)	$ (17,865)	$ (36,913)
Denominator:				
Weighted average common shares outstanding	6,423,182	4,302,520	6,422,242	4,053,883
Net loss per share attributable to common stockholders – basic and diluted	$ (1.06)	$ (5.84)	$ (2.78)	$ (9.11)

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, 2024 and 2023 because they were antidilutive, out-of-the-money, or the issuance of such shares is contingent upon certain conditions which were not satisfied by the end of the period:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Convertible notes payable (see Note 8)	62,500	86,635	62,500	86,635
Common stock warrants (see Note 13)	5,271,604	5,271,604	5,271,604	5,271,604
Options to purchase common stock (see Note 11)	1,825,429	1,060,061	1,825,429	1,060,061
Unvested restricted stock awards (see Note 11)	38,363	40,052	38,363	40,052
Contingent earn-out shares (see Note 2)	329,628	329,628	329,628	329,628
Total	7,527,524	6,787,980	7,527,524	6,787,980

Note 15. Related Party Transactions

License and Supply Agreements

In August 2018, we entered into a license agreement (the "License Agreement") and exclusive supply agreement (the "Supply Agreement") in conjunction with 4Life's investment in the Series C preferred stock and warrants of our predecessor. On April 25, 2024, we entered into an amendment to the License Agreement and Supply 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 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. The Company may permanently convert 4Life's exclusive rights to purchase Licensed Products to non-exclusive rights if: (i) 4Life fails to achieve the Minimum Sales Commitment for any two consecutive years, and (ii) 4Life fails to pay additional royalty fees to maintain exclusivity (as set forth under "*License Agreement*" below) (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. If 4Life fails to meet the Exclusivity Provision, 4Life may continue to maintain exclusivity by paying 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. However, notwithstanding any other provisions of the License Agreement, on or after January 1, 2027, we shall be permitted to sell Licensed Products through third party retail outlets or via our own websites. 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 will be renewable for additional five-year terms upon mutual agreement of the parties.

We currently provide an aqueous zinc-silver ion dietary (mineral) supplement to 4Life, which is sold by 4Life under the tradename Zinc Factor™; and an aqueous gold dietary (mineral) supplement of very low-concentration gold nanoparticles, which is sold by 4Life under the tradename Gold Factor™. Total revenue under the License and Supply Agreements during the three and six months ended June 30, 2024 and 2023 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2024	2023	2024	2023
Product revenue from related parties	$ 64	$ 193	$ 107	$ 256
Royalty revenue from related parties	27	43	56	86
Total revenue from related parties	$ 91	$ 236	$ 163	$ 342

Note 16. Subsequent Events

On July 11, 2024 we effected the Reverse Stock Split, pursuant to which every 20 shares of our Common Stock issued and outstanding were automatically combined and converted into 1 validly issued, fully paid and non-assessable share of Common Stock. For a description of the Reverse Stock Split, refer to *Note 2. Summary of Significant Accounting Policies—Reverse Stock Split*.

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 condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements reflecting our or our management team's expectations, hopes, beliefs, intentions, strategies, estimates, and assumptions concerning events and financial trends that may affect our future financial condition or results of 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. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the section titled "Risk Factors" in our Annual Report on Form 10-K. 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. 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, material science, and biochemistry. Our platform process results in nanocrystals with faceted structures and surfaces that are free of the chemical surface modifications that accompany other production methods. Many traditional methods of nanoparticle synthesis involve the unavoidable deposition of potentially toxic organic residues and stabilizing surfactants on the particle surfaces. Synthesizing stable nanocrystals that are both nontoxic and highly catalytic has overcome this significant hurdle in harnessing transition metal catalytic activity for therapeutic use. Our clean-surfaced nanocrystals exhibit catalytic activities many-fold higher than multiple other commercially available nanoparticles, produced using various techniques, that we have comparatively evaluated.

We have multiple drug assets currently in development and/or clinical trials for applications primarily in neurology. Our development and clinical efforts are currently focused on addressing the high unmet medical needs in central nervous system disorders including amyotrophic lateral sclerosis ("ALS"), multiple sclerosis ("MS"), and Parkinson's disease ("PD"). We currently have no drugs approved for commercial sale and have not generated any revenue from drug sales. We have never been profitable and have incurred operating losses in each year since inception. We generate revenue from sales of dietary supplements through our wholly owned subsidiary, dOrbital, Inc., or through an exclusive license with 4Life Research LLC ("4Life"), an international supplier of health supplements, stockholder, and related party. We anticipate these revenues to be small compared to our operating expenses and to the revenue we expect to generate from potential future sales of our drug candidates, for which we are currently conducting clinical trials.

Reverse Recapitalization

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

In connection with the Reverse Recapitalization, certain of Clene Nanomedicine's common stockholders are entitled to receive earn-out payments (the "Clene Nanomedicine Contingent Earn-out"), and Tottenham's former officers and directors and Norwich Investment Limited (collectively, the "Initial Stockholders") are entitled to receive earn-out payments (the "Initial Stockholders Contingent Earn-out," and both collectively the "Contingent Earn-outs") based on achieving certain milestones.

Reverse Stock Split

Effective July 11, 2024 (the "Effective Date"), we filed a Certificate of Amendment to our Fourth Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, to effect a 1-for-20 reverse stock split (the "Reverse Stock Split") of our Common Stock. Beginning with the opening of trading on the Effective Date, our Common Stock began trading on Nasdaq on a split-adjusted basis under the same symbol, "CLNN." As a result of the Reverse Stock Split, every 20 shares of our Common Stock issued and outstanding were automatically combined and converted into 1 validly issued, fully paid and non-assessable share of Common Stock. In lieu of any fractional shares, stockholders received an amount in cash (without interest) equal to: (i) the number of shares of Common Stock held by such stockholder before the Reverse Stock Split that would otherwise have been exchanged for such fractional shares multiplied by (ii) the closing price of our Common Stock on Nasdaq on the trading day immediately preceding the Effective Date.

The Reverse Stock Split did not reduce the total number of authorized shares of Common Stock or preferred stock, par value $0.0001 per share ("Preferred Stock"), or change the par values of the Company's Common Stock or Preferred Stock. All outstanding stock options, warrants, rights to restricted stock awards, convertible debt, and contingent earn-out shares entitling their holders to purchase or receive shares of Common Stock were adjusted as a result of the Reverse Stock Split, in accordance with the terms of each such security. In addition, the number of shares reserved for issuance pursuant to our Amended 2020 Stock Plan was also appropriately adjusted. All historical share and per share data for the periods presented in our condensed consolidated financial statements, including for periods ending prior to July 11, 2024, has been adjusted to reflect the 1-for-20 Reverse Stock Split on a retroactive basis as if the Reverse Stock Split occurred as of the earliest period presented.

Recent Developments of Our Clinical Programs

Amyotrophic Lateral Sclerosis

In June 2024, we announced new long-term CNM-Au8 treatment results for survival and NfL levels from the HEALEY ALS Platform Trial open label extension ("OLE"). The data highlights up to 42 months of survival follow-up and 76 weeks of long-term NfL biomarker results, including a neurofilament light ("NfL") responder subset (the "CNM-Au8 NfL Responders") from the HEALEY ALS Platform Trial who had consistent and sustained NfL reductions, comprising nearly half of all CNM-Au8 patients. All participants treated with CNM-Au8 30 mg, including ex-placebo participants who transitioned to CNM-Au8 in the OLE, with complete baseline co-variates were included in the survival analysis:

- **Improved Survival Compared to Matched PRO-ACT Controls:** Survival analyses of participants originally randomized to CNM-Au8 30 mg treatment (n=59) and ex-placebo to CNM-Au8 (n=11) compared to matched PRO-ACT controls up to 3.5 years post-baseline.
    - Approximately 60% decreased risk of death in CNM-Au8 30 mg treated patients compared to matched PRO-ACT controls up to 3.5 years of follow-up; covariate-adjusted hazard ratio ("HR"): 0.431 (95% CI: 0.276-0.672), p-value = 0.0002.
- **Reduced NfL Biomarker Levels in CNM-Au8 NfL Responders:** CNM-Au8 NfL Responder Subset: The CNM-Au8 NfL Responder analysis was completed to identify NfL decreases in participants who showed consistent NfL declines (n=55). CNM-Au8 NfL Responders were defined as participants who had all post-baseline measures with an NfL decrease or repeated declines of at least 10 pg/mL following the start of CNM-Au8 treatment.
    - CNM-Au8 NfL Responders demonstrated an average NfL reduction of 28%, which is suggestive of decreased axonal loss on an ongoing basis; geometric mean ratio ("GMR") at week 76 change vs. baseline: 0.72, (95% CI: 0.67 – 0.79), $p < 0.0001$.
    - The NfL results are based on earlier announced analyses of plasma NfL collected from participants (n=99) in the OLE who were treated with CNM-Au8 30 mg through week 76 compared to participants treated with placebo for 24 weeks prior to crossing over to active treatment for up to 52 weeks. Long-term treatment with CNM-Au8 30 mg resulted in continued significant decline of plasma NfL levels. The GMR vs. placebo at week 76 was 0.841, 95% CI: 0.73 – 0.98, p = 0.023.

CNM-Au8 was well-tolerated and no significant safety findings were observed in the OLE.

On July 13, 2024, we submitted a briefing book to the U.S. Food and Drug Administration ("FDA") in advance of a granted Type C interaction expected to occur in the third quarter of 2024. The briefing book contains new *post-hoc* analyses from two independently conducted Phase 2 clinical trials of CNM-Au8® for the treatment for ALS. This new information supplements the original data previously discussed with the FDA in late 2023 and is intended to guide the planned FDA Type C interaction expected to occur in the third quarter of 2024 to discuss an accelerated approval regulatory pathway. We plan to publicly announce the topline FDA feedback following the conclusion of the Type C interaction. CNM-Au8 NfL Responders demonstrated a 28% mean reduction in NfL levels compared to baseline, while NfL levels continued to increase in CNM-Au8 NfL non-responders (all doses; GMR difference at week 76 post-baseline: 0.57, 95% CI: 0.50 – 0.64, $p < 0.00001$). The analyses of the CNM-Au8 NfL Responders demonstrated efficacy in all-cause mortality, function, and combined assessment of function and survival ("CAFS"):

- All-cause mortality (survival):
  - Improved survival of CNM-Au8 NfL Responders compared to propensity matched controls from the PRO-ACT database: HR: 0.504, 95% Wald CI: 0.28 – 0.904, covariate adjusted, $p = 0.022$.
  - Improved survival of CNM-Au8 NfL Responders compared to CNM-Au8 NfL non-responders: HR: 0.350, 95% CI: 0.188 – 0.649, covariate adjusted, $p = 0.0009$.
- ALS Functional Improvement: the ALS Functional Rating Scale ("ALSFRS-R") is an instrument for evaluating the functional status of patients with ALS and is used to monitor functional change in a patient over time. CNM-Au8 NfL Responders demonstrated:
  - Significantly less decline in ALSFRS-R total score compared to CNM-Au8 NfL non-responders: $p < 0.01$ at the week 64, 76, 88, and 100 visits post-randomization (mixed model repeated measures ("MMRM") was used to compare least squares mean change from baseline).
  - Significantly less decline in the respiratory subdomain score of the ALSFRS-R compared to CNM-Au8 NfL non-responders: $p < 0.01$ at the week 64, 76, 88, and 100 visits post-randomization (MMRM was used to compare least squares mean change from baseline).
- Improvements in the Combined Assessment of Function and Survival: CAFS ranks clinical outcomes based on survival time and change in the ALSFRS-R:
  - CNM-Au8 NfL Responders demonstrated improvements compared to CNM-Au8 NfL non-responders starting at week 48 ($p < 0.10$) and all later timepoints with significance reached at weeks 88 and later ($p < 0.05$).

Independent of NfL responder status, long-term treatment with CNM-Au8 30 mg was associated with improved survival in participants from the RESCUE-ALS and HEALEY ALS Platform Trials using updated long-term follow-up of survival status compared to propensity matched controls from the clinical trial data registry PRO-ACT, the ALS/MND Natural History Consortium ("NHC"), and the Australian MiNDAUS registry. Matching methods and covariates were prespecified and conducted by an independent statistician.

- Long-term treatment with CNM-Au8 30 mg in the HEALEY ALS Platform Trial demonstrated a 57% decreased risk of all-cause mortality vs. PRO-ACT propensity matched controls: (HR: 0.431, 95% CI: 0.276 to 0.672; covariate adjusted, $p = 0.0002$).
- Long-term treatment with CNM-Au8 30 mg in the HEALEY ALS Platform Trial demonstrated a 48% decreased risk of all-cause mortality vs. ALS NHC propensity matched controls: (HR: 0.519, 95% CI: 0.347 to 0.776; covariate adjusted, $p = 0.0014$).
- Long-term treatment with CNM-Au8 30 mg in the RESCUE-ALS Phase 2 Trial demonstrated a 70% decreased risk of all-cause mortality vs. PRO-ACT propensity matched controls: (HR: 0.311, 95% CI: 0.142 to 0.682; covariate adjusted, $p = 0.0035$).
- Long-term treatment with CNM-Au8 30 mg in the RESCUE-ALS Phase 2 Trial demonstrated a 51% decreased risk of all-cause mortality vs. MiNDAUS propensity matched controls: (HR: 0.487, 95% CI: 0.287 to 0.824; covariate adjusted, $p = 0.0074$).

Further, CNM-Au8 mechanism of action responders demonstrated concordance with CNM-Au8 NfL Responders. Data provided to the FDA also included an association of responses between CNM-Au8 mechanism responders (defined as those who had consistent and sustained NAD+ and GSH/GGSG glutathione improvements) and CNM-Au8 NfL Responders. The connection between CNM-Au8 mechanism responders and CNM-Au8 NfL Responders links the mechanism of action to NfL declines. Biomarkers of oxidative stress, including the GSH/GSSG ratio, demonstrated consistent improvement following CNM-Au8 treatment with increased activity associated with the duration of treatment. These data support a dual mechanism of action of neuronal metabolic support and decreased oxidative stress. We further provided mechanistic evidence from preclinical models that established improved neuronal integrity and survival, where CNM-Au8 simultaneously decreased the release of NfL from damaged motor neurons axons.

We are also planning the design of an international Phase 3 trial of CNM-Au8 30 mg, RESTORE-ALS, with expert ALS clinical advisors and expect to initiate the trial in the second quarter of 2025, contingent upon funding. We plan to work closely with regulatory health authorities from the FDA, European Medicines Agency ("EMA"), ALS experts, and patient representatives to determine the proper path to support potential approval.

Multiple Sclerosis

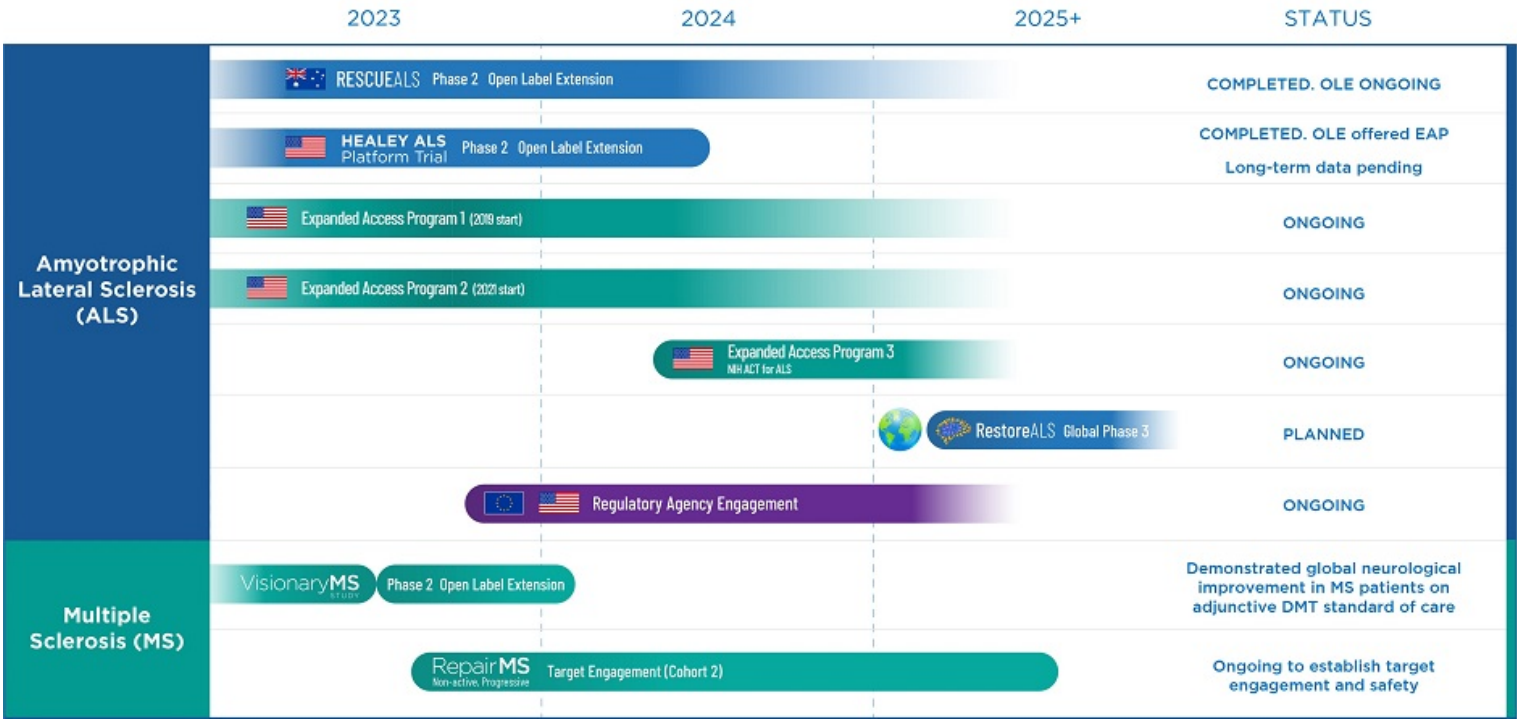
In April 2024, we announced the latest data from the open label long-term extension ("LTE") of our Phase 2 VISIONARY-MS clinical trial at the 2024 American Academy of Neurology Annual Meeting. These new long-term results across multiple paraclinical exploratory endpoints reinforce the evidence for sustained clinical benefit to trial participants across multiple clinical outcome measures associated with consistent improvements in neuronal function and remyelination. The LTE results demonstrate evidence supporting repair and remyelinating effects of CNM-Au8 treatment in patients originally randomized to CNM-Au8 and further enhance the trial's results from the double-blind period, which demonstrated significant improvements in the primary and secondary endpoints, low contrast letter acuity ("LCLA") and the modified MS Functional Rating Scale, respectively. The key LTE results include the following:

- Clinical improvements in cognition and vision:
  - Participants originally randomized to CNM-Au8 treatment experienced continued significant improvement in vision as measured by LCLA. More than half of participants improved by 10 or more letters on a low-contrast Sloan eye chart, with increases of up to 38 letters (mixed model repeat measures, or MMRM, vs. original baseline, $p < 0.001$).
  - Participants originally randomized to placebo who transitioned to CNM-Au8 after the 48-week double-blind period into the LTE also experienced significant improvement in vision as measured by LCLA following treatment with 30 mg CNM-Au8 (MMRM vs. original baseline, $p < 0.05$).
  - Participants treated with CNM-Au8 experienced up to 29 points of significant improvement (max score =110) in cognition and working memory as measured by the Symbol Digit Modality Test ("SDMT") (MMRM vs. original baseline, $p < 0.001$).
- Physiologic functional evidence of repair and remyelination:
  - Participants treated with CNM-Au8 experienced significant improvements in both amplitude (MMRM vs. original baseline, $p < 0.01$) and latency (MMRM vs. original baseline, $p = 0.06$) as measured by multi-focal visual evoked potentials, physiologic measures of signal strength and speed along the visual pathway, markers of neuronal health and remyelination, respectively.
- Structural evidence of repair and remyelination:
  - Magnetic resonance imaging ("MRI") measures of axial diffusivity showed significant improvements in T2 brain lesions in participants treated with CNM-Au8 (MMRM vs. original baseline, $p < 0.05$).
  - MRI measures of T2 lesion myelin water fraction ("MWF") and magnetization transfer ratio ("MTR"), markers of remyelination, improved with long-term CNM-Au8 treatment (MWF: MMRM vs. original baseline, $p < 0.05$; MTR: MMRM vs. original baseline, $p = 0.06$).

CNM-Au8 was well-tolerated and no significant safety findings were observed.

We have initiated a second dosing cohort of REPAIR-MS, an open-label, investigator blinded Phase 2 clinical trial in non-active progressive MS patients. We anticipate enrollment concluding in by the end of 2024 with topline results available by mid-2025. We plan to work closely with regulatory health authorities from the FDA and EMA, MS experts, and patient representatives to determine the proper path to advance CNM-Au8 into Phase 3 and potential future approval. We expect to meet with the FDA in an end of Phase 2 meeting in the first half of 2025.

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



Recent Competition Update

Despite the great need for an effective disease-modifying treatment for ALS and significant research efforts by the pharmaceutical industry to meet this need, there have been limited clinical successes and no curative therapies approved to date. In April 2023, the FDA granted accelerated approval to tofersen, branded as Qalsody, a drug from Biogen Inc. for the treatment of SOD1-ALS, a rare genetic form of ALS. In May 2024, the European Commission granted marketing authorization under exceptional circumstances for Qalsody in the European Union. Additionally, sodium phenylbutyrate and taurursodiol, a drug from Amylyx Pharmaceuticals, Inc. ("Amylyx") which previously received approval from the FDA and conditional approval from Health Canada based on the results of a Phase 2 trial, was voluntarily withdrawn from the market in the U.S. and Canada following the negative outcome of a Phase 3 clinical trial.

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 Expense

The discovery and development of novel drug candidates require 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 CNM-Au8, our lead asset, with the remainder spent on our CNM-ZnAg asset.

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 decrease throughout 2024 as we complete our Phase 2 clinical trials and will increase in future years as we advance our assets into Phase 3. Additionally, if we are able to file a new drug application ("NDA") under an accelerated pathway with the FDA, contingent upon our Type C interaction with the FDA which will occur in the third quarter of 2024 as discussed above under *Recent Developments of Our Clinical Programs*, 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 and materials expenses to support our clinical trials; payments to CROs, principal investigators, and clinical trial sites; costs of preclinical activities; consulting costs; and allocated overhead costs, including rent, equipment, utilities, depreciation, insurance, and facilities maintenance. 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.

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 Expense

General and administrative expenses consist primarily of payroll and personnel expenses for salaries, benefits, and stock-based compensation; fees for legal, accounting, tax, and information technology services; fees for directors' and officers' insurance; expenses for business development activities and investor and public relations; rent, utilities, and facility costs; travel costs; and consulting fees.

We anticipate that our general and administrative expenses in future periods will be contingent upon our discussions with the FDA, expected in the third quarter of 2024. If we are able to file an NDA with the FDA based on our accumulation of clinical evidence, 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 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 based on our FDA interaction, 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 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) commitment share expense from shares of Common Stock issued as a commitment fee, (iii) changes in the fair value of our (a) common stock warrant liabilities and (b) Contingent Earn-outs, (iv) research and development tax credits, unconditional grants, and conditional grants for which applicable conditions have been met, and (v) realized gains and losses on foreign currency transactions and other miscellaneous income and expense items.

Results of Operations

Our results of operations for the three and six months ended June 30, 2024 and 2023 were as follows:

(in thousands)	Three Months Ended June 30, 2024	2023	Change	Six Months Ended June 30, 2024	2023	Change
Revenue:						
Product revenue	$ 64	$ 226	(72)%	$ 108	$ 290	(63)%
Royalty revenue	27	43	(37)%	56	86	(35)%
Total revenue	91	269	(66)%	164	376	(56)%
Operating expenses:						
Cost of revenue	18	66	(73)%	34	71	(52)%
Research and development	4,150	6,615	(37)%	10,019	14,010	(28)%
General and administrative	3,314	3,924	(16)%	6,734	7,363	(9)%
Total operating expenses	7,482	10,605	(29)%	16,787	21,444	(22)%
Loss from operations	(7,391)	(10,336)	(28)%	(16,623)	(21,068)	(21)%
Total other income (expense), net	606	(14,807)	*	(1,242)	(15,845)	(92)%
Net loss	$ (6,785)	$ (25,143)	(73)%	$ (17,865)	$ (36,913)	(52)%

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, 2024 and 2023, changes in product and royalty revenues were due to the timing of purchases 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 Expense

Research and development expense during the three and six months ended June 30, 2024 and 2023 was as follows:

(in thousands)	Three Months Ended June 30, 2024	2023	Change	Six Months Ended June 30, 2024	2023	Change
CNM-Au8	$ (720)	$ 1,832	*	$ 331	$ 3,965	(92)%
CNM-ZnAg	—	116	*	13	929	(99)%
Unallocated	1,422	1,221	16%	2,686	2,380	13%
Personnel	2,545	2,322	10%	5,209	4,639	12%
Stock-based compensation	903	1,124	(20)%	1,780	2,097	(15)%
Total research and development	$ 4,150	$ 6,615	(37)%	$ 10,019	$ 14,010	(28)%

* 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: (i) reimbursements received during the three and six months ended June 30, 2024 for expenses incurred since September 2023 from our ongoing ALS expanded access program ("EAP") funded by a National Institute of Health grant (the "ACT-EAP"), for which reimbursements are recorded as an offset to research and development expense, (ii) a decrease in expenses in the HEALEY ALS Platform Trial, RESCUE-ALS, REPAIR-MS, and VISIONARY-MS clinical trials due to the previous completion of the blinded period of each trial, and (iii) a decrease in expenses for the VISIONARY-MS LTE due to its completion; partially offset by an increase in expenses related to: (A) our two ALS EAPs with Massachusetts General Hospital due to increased enrollment and expansion of one EAP, (B) planning activities for our RESTORE-ALS clinical trial, and (C) increased non-clinical, pre-clinical and regulatory activities;

(ii) a decrease in expenses related to CNM-ZnAg, primarily due to completion of the clinical trial for treatment of COVID-19 in late 2022 with expenses continuing through 2023;

(iii) an increase in unallocated expenses, primarily due to increased expenses related to research, manufacturing, equipment, and materials;

(iv) an increase in personnel expenses, primarily due to an increase in compensation expense related to the ACT-EAP and our regulatory activities; and

(v) a decrease in stock-based compensation expense, primarily due to the timing of award grants, vesting, and forfeitures for research and development personnel.

General and Administrative Expense

General and administrative expense during the three and six months ended June 30, 2024 and 2023 was as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	**2024**	**2023**	**Change**	**2024**	**2023**	**Change**
Directors' and officers' insurance	$ 187	$ 399	(53)%	$ 373	$ 797	(53)%
Legal	284	153	86%	359	261	38%
Finance and accounting	124	459	(73)%	373	718	(48)%
Public and investor relations	199	124	60%	433	268	62%
Personnel	1,044	1,184	(12)%	2,140	2,173	(2)%
Stock-based compensation	1,048	1,327	(21)%	2,184	2,577	(15)%
Other	428	278	54%	872	569	53%
Total general and administrative	$ 3,314	$ 3,924	(16)%	$ 6,734	$ 7,363	(9)%

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

(i) a decrease in directors' and officers' insurance fees;

(ii) an increase in legal fees, primarily due to an increase in legal fees related to regulatory activities, the ACT-EAP, and intellectual property; partially offset by a decrease in legal fees related to financing and fundraising;

(iii) a decrease in finance and accounting fees, primarily due to a decrease in fees from consultants, advisors, and other financial vendors; partially offset by increased tax and audit fees;

(iv) an increase in fees related to our public and investor relations efforts;

(v) a decrease in stock-based compensation expense, primarily due to the timing of award grants, vesting, and forfeitures for general and administrative personnel; and

(vi) an increase in other expenses, primarily due to an increase in expenses related to lobbying activities and office and professional expenses; partially offset by a decrease in expenses related to supplies and equipment, property and casualty insurance, leased facilities, and travel.

Total Other Income (Expense), Net

Total other income (expense), net, during the three and six months ended June 30, 2024 and 2023 was as follows:

(in thousands)	Three Months Ended June 30, 2024	2023	Change	Six Months Ended June 30, 2024	2023	Change
Interest income	$ 269	$ 213	26%	$ 628	$ 385	63%
Interest expense	(1,282)	(1,104)	16%	(2,526)	(2,170)	16%
Commitment share expense	—	(3)	*	—	(402)	*
Issuance costs for common stock warrant liabilities	—	(333)	*	—	(333)	*
Loss on initial issuance of equity	—	(14,840)	*	—	(14,840)	*
Change in fair value of common stock warrant liabilities	1,568	(383)	*	259	(383)	*
Change in fair value of Clene Nanomedicine contingent earn-out liability	22	1,165	(98)%	75	1,110	(93)%
Change in fair value of Initial Stockholders contingent earn-out liability	3	150	(98)%	10	143	(93)%
Research and development tax credits and unrestricted grants	26	341	(92)%	312	655	(52)%
Other expense, net	—	(13)	*	—	(10)	*
Total other income (expense), net	$ 606	$ (14,807)	*	$ (1,242)	$ (15,845)	(92)%

* Not meaningful.

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

(i) an increase in interest income primarily due to increasing interest rates and higher investment returns on cash, cash equivalents, and marketable securities; and an increase in interest expense primarily due to increasing interest rates and increased amortization of debt discount and debt issuance costs on notes payable;

(ii) commitment share expense, due to the shares of Common Stock issued to Lincoln Park Capital Fund, LLC ("Lincoln Park"), as an initial fee for Lincoln Park's commitment to purchase shares of Common Stock under a purchase agreement with the Company during the three and six months ended June 30, 2023;

(iii) issuance costs from a public equity offering allocated to liability-classified warrants during the three and six months ended June 30, 2023;

(iv) a loss on initial issuance of equity from the fair value in excess of proceeds from a public equity offering during the three and six months ended June 30, 2023;

(v) a gain from a change in fair value of the common stock warrant liability due to the New Avenue Warrant and Tranche A Warrants during the three and six months ended June 30, 2024. The changes in fair value were due to the change in price of our Common Stock on Nasdaq and updates in the valuation model assumptions (see "*Critical Accounting Estimates*");

(vi) a gain from a change in fair value of the Clene Nanomedicine Contingent Earn-out liability and Initial Stockholders Contingent Earn-out liability during the three and six months ended June 30, 2024. The changes were due to the price of our Common Stock on Nasdaq and updates in the valuation model assumptions (see "*Critical Accounting Estimates*"); and

(vii) a decrease in research and development tax credits and unrestricted grants due to changes in the amount of qualifying research and development expenses incurred.

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 4.65% and 4.85% for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024 and December 31, 2023, 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, 2024 and 2023. We recorded other income of $40,000 and $0.7 million for the six months ended June 30, 2024 and 2023, respectively, for research and development tax credits pertaining to Clene Australia for the 2024 and 2023 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. Clene Netherlands had no taxable income or provision for income taxes for the six months ended June 30, 2024 and 2023.

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 revenues from our products to offset expenses and capital expenditures. In the event that we do not generate sufficient revenues 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 $175.2 million from equity financing, including sales of common stock, preferred stock, warrants to purchase common stock;
- gross proceeds of $32.3 million from borrowings under convertible promissory notes;
- gross proceeds of $27.3 million from borrowings under notes payable and convertible notes payable;
- gross proceeds of $9.4 million from the Reverse Recapitalization;
- gross proceeds of $9.1 million from refundable research and development tax credits;
- gross proceeds of $6.0 million from grants from various organizations; and
- gross proceeds of $1.0 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 a platform trial for the treatment of ALS with certain drug candidates, including CNM-Au8, 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 $7.4 million and $10.3 million for the three months ended June 30, 2024 and 2023, respectively; and $16.6 million and $21.1 million for the six months ended June 30, 2024 and 2023, respectively. Our accumulated deficit was $260.6 million and $242.7 million as of June 30, 2024 and December 31, 2023, respectively. Our cash, cash equivalents, and marketable securities totaled $21.7 million and $35.0 million as of June 30, 2024 and December 31, 2023, respectively, and net cash used in operating activities was $13.4 million and $16.2 million for the six months ended June 30, 2024 and 2023, respectively.

We have incurred significant losses and negative cash flows from operations since our inception. We have not generated significant revenues since our inception, and we do not anticipate generating significant revenues unless we successfully complete development and obtain regulatory approval for commercialization of a drug candidate. We expect to incur additional losses in the future, particularly as we advance the development of our clinical-stage drug candidates, continue research and development of our preclinical drug candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our term loan with Avenue Venture Opportunities Fund, L.P. (“Avenue”), we are required to maintain unrestricted cash and cash equivalents of at least $5.0 million to avoid acceleration of the full balance of the loan (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 equity purchase agreement and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. We have implemented cost-saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts and elimination of certain staff positions. We have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date the condensed consolidated financial statements 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; and general and administrative costs to support our drug development and pre-commercial activities in advance of receiving regulatory approval for our drug candidates. Firm commitments for funds include approximately $1.1 million of payments under operating lease obligations; payment of principal and interest on notes payable totaling $22.0 million; and commitments under various agreements for capital expenditures totaling $0.2 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.

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; and general and administrative costs to support our drug development activities in advance of receiving regulatory approval for our drug candidates. Additional funds may be spent to initiate new clinical trials, at our discretion. Known obligations beyond the next twelve months include $5.8 million of payments under operating lease obligations, and interest and principal repayment of notes payable of $7.9 million. We expect to meet our long-term liquidity requirements primarily through equity financing, debt financing, or other capital sources.

Use of Funds

Our cash flows for the six months ended June 30, 2024 and 2023 were as follows:

(in thousands)	Six Months Ended June 30, 2024	2023
Net cash used in operating activities	$ (13,438)	$ (16,239)
Net cash provided by investing activities	6,319	4,761
Net cash provided by financing activities	9	42,418
Effect of foreign exchange rate changes on cash	(29)	(29)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (7,139)	$ 30,911

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 $13.4 million for the six months ended June 30, 2024, which resulted from a net loss of $17.9 million, adjusted for non-cash items totaling $5.4 million and a net change in operating assets and liabilities of $0.9 million. Significant non-cash items included: (i) depreciation expense of $0.8 million for laboratory and office equipment and leasehold improvements; (ii) non-cash lease expense of $0.3 million; (iii) stock-based compensation expense of $4.0 million; (iv) accretion of debt discount of $0.8 million; (v) non-cash interest expense of $28,000; (vi) non-cash interest income on marketable securities of $0.2 million; (vii) a change in fair value of common stock warrant liabilities of $0.3 million due to changes in price of our Common Stock on Nasdaq and changes in valuation model inputs; and (viii) a change in fair value of the Clene Nanomedicine and Initial Stockholders Contingent Earn-outs of $0.1 million and $10,000, respectively, due to changes in price of our Common Stock on Nasdaq and changes in valuation model inputs. The net change in operating assets and liabilities was primarily attributable to: (a) 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; (b) an increase in prepaid expenses and other current assets of $2.5 million due to the timing of vendor invoicing and payments, the timing of receipt of metals to be used in research and development, an increase in prepaid ACT-EAP expenses, and an increase in research and development tax credits receivable; (c) an increase in accrued liabilities of $2.2 million primarily due to increased accrued compensation and benefits and increased deferred grants, partially offset by a decrease in accrued CRO and clinical fees; and (d) a decrease in operating lease obligations of $0.3 million.

Net cash used in operating activities was $16.2 million for the six months ended June 30, 2023, which resulted from a net loss of $36.9 million, adjusted for non-cash items totaling $21.1 million and a net change in operating assets and liabilities of $0.5 million. Significant non-cash items included: (i) depreciation expense of $0.8 million for laboratory and office equipment and leasehold improvements; (ii) non-cash lease expense of $0.2 million; (iii) commitment share expense of $0.4 million for shares of Common Stock issued to Lincoln Park as an initial fee for their commitment to purchase shares of our Common Stock under a purchase agreement; (iv) issuance costs of $0.3 million for liability-classified warrants issued in a public equity offering; (v) a loss on initial issuance of equity of $14.8 million from the fair value in excess of proceeds from a public equity offering; (vi) stock-based compensation expense of $4.7 million; (vii) accretion of debt discount of $0.5 million; (viii) non-cash interest expense of $0.2 million; (ix) a change in fair value of the Clene Nanomedicine and Initial Stockholders Contingent Earn-outs of $1.1 million and $0.1 million, respectively, due to the decrease in price of our Common Stock on Nasdaq and changes in valuation model inputs; and (x) a change in fair value of common stock warrant liabilities of $0.4 million due to the increase in price of our Common Stock on Nasdaq between the issuance date and reporting date and changes in valuation model inputs. The net change in operating assets and liabilities was primarily attributable to: (a) a decrease in accounts receivable of $28,000 and a decrease in accounts payable of $2.2 million due to the timing of vendor invoicing and payments; (b) an increase in inventory of $9,000; (c) a decrease in prepaid expenses and other current assets of $1.7 million due to the timing of vendor invoicing and payments, the timing of receipt of metals to be used in research and development, and a decrease in research and development tax credits receivable; (d) an increase in accrued liabilities of $0.2 million primarily due to increased CRO and clinical fees, partially offset by decreased accrued compensation and benefits; and (e) a decrease in operating lease obligations of $0.3 million.

Investing Activities

Net cash provided by investing activities was $6.3 million for the six months ended June 30, 2024, which consisted of proceeds from maturities of marketable securities of $12.5 million, partially offset by purchases of marketable securities of $6.2 million and purchases of property and equipment of $13,000. Net cash provided by investing activities was $4.8 million for the six months ended June 30, 2023, which consisted of proceeds from maturity of marketable securities of $5.0 million, partially offset by purchases of property and equipment of $0.2 million.

Financing Activities

Net cash provided by financing activities was $9,000 for the six months ended June 30, 2024, which consisted of proceeds from the exercise of stock options of $36,000, partially offset by payments of finance lease obligations of $27,000. Net cash provided by financing activities was $42.4 million for the six months ended June 30, 2023, which consisted of proceeds from issuance of common stock, net of offering costs, of $42.1 million, and proceeds from the issuance of notes payable of $0.4 million; partially offset by payments of finance lease obligations of $46,000.

Public Offering

In June 2023, we sold 2,500,000 units at a sale price of $16.00 per unit pursuant to an underwriting agreement with Canaccord Genuity LLC ("Canaccord"). Each unit consisted of (i) one share of Common Stock, (ii) one warrant to purchase one share of Common Stock at an exercise price of $22.00 per share (the "Tranche A Warrants"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $30.00 per share (the "Tranche B Warrants"). The aggregate gross proceeds were $40.0 million, excluding the proceeds, if any, from the exercise of the Tranche A and Tranche B Warrants. We cannot predict when or if the Tranche A or Tranche B Warrants will be exercised, and it is possible they may expire and/or never be exercised. We paid underwriting discounts and commissions of $2.4 million and offering expenses of $0.2 million. The offering was made pursuant to our registration statement on Form S-3 (file number 333-264299), which was declared effective by the SEC on April 26, 2022, a related registration statement pursuant to Rule 462(b) (file number 333-272692), filed with the SEC and effective on June 16, 2023, and our prospectus supplement relating to the offering.

Common Stock Sales Agreement

During the three and six months ended June 30, 2023, we sold 0 and 144,755 shares of Common Stock, respectively, under our Equity Distribution Agreement (the "ATM Agreement") with Canaccord; generated gross proceeds of $0 and $4.5 million, respectively; and paid commissions of $0 and $0.1 million, respectively. We did not sell any shares during the three and six months ended June 30, 2024. The sale of Common Stock under the ATM Agreement was made pursuant to our registration statement on Form S-3 (file number 333-264299), which was declared effective by the Securities and Exchange Commission on April 26, 2022. We subsequently terminated and filed a new prospectus supplement relating to the offering, which was most recently amended on May 8, 2024, for the future offer and sale of Common Stock having an aggregate offering price of up to $12.3 million.

Common Stock Purchase Agreement

During the three and six months ended June 30, 2023, we sold 20,000 shares of Common Stock under our purchase agreement (the "Purchase Agreement") with Lincoln Park, issued 145 Additional Commitment Shares, and generated gross proceeds of $0.4 million. We did not sell any shares during the three and six months ended June 30, 2024. The sale of Common Stock under the Purchase Agreement was made pursuant to our registration statement on Form S-3 (file number 333-264299), which was declared effective by the SEC on April 26, 2022. On June 16, 2023, we suspended and terminated the prospectus supplement (the "Purchase Agreement Prospectus Supplement") related to the offering with respect to the unsold shares of Common Stock issuable pursuant to the Purchase Agreement. We will not make any further sales of our securities pursuant to the Purchase Agreement, unless and until a new prospectus supplement is filed. Other than the termination of the Purchase Agreement Prospectus Supplement and offering with respect to future sales by us, the Purchase Agreement remains in full force and effect.

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 a portion of the 2021 Avenue Loan as convertible notes payable in the condensed consolidated balance sheets as of December 31, 2023 and did not separate the conversion option from the host contract as it did not meet the requirements for accounting as a derivative instrument. As of June 30, 2024, the conversion option has expired. We accounted for the convertible note as a single liability measured at its amortized cost as December 31, 2023 with a carrying value of $4.9 million.

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, 2024 and December 31, 2023, the convertible note was carried at $5.3 million and $5.3 million, respectively.

Common Stock Warrant Liabilities

Pursuant to a June 2023 amendment to the 2021 Avenue Loan, we issued a warrant to purchase 150,000 shares of Common Stock at $16.00 per share (the "New Avenue Warrant"). In accordance with ASC 815, we recognized the New Avenue Warrant as a derivative liability measured at fair value and remeasure the New Avenue Warrant 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 New Avenue Warrant resulted in a gain of $0.1 million and a loss of $0.1 million during the three months ended June 30, 2024 and 2023, respectively; and a loss of $0.1 million and a loss of $0.1 million during the six months ended June 30, 2024 and 2023, respectively. We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of the following events: (i) settlement of the instrument upon a change of control transaction, (ii) dissolution of the Company, or (iii) another outcome outside of (i)-(ii). These estimates require significant judgment. As of June 30, 2024 and December 31, 2023, the unobservable inputs were as follows:

	June 30, 2024	December 31, 2023
Expected stock price volatility	79.00% –99.80%	105.00% –110.00%
Risk-free interest rate	4.40% –5.40%	3.88% –5.03%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	0.42 –4.00	0.75 –4.50
Probability of change of control	10.00%	25.00%
Probability of dissolution	55.00%	50.00%
Probability of other outcome	35.00%	25.00%

Pursuant to an underwritten public offering in June 2023, we issued the Tranche A Warrants to purchase 2,500,000 shares of Common Stock at $22.00 per share. In accordance with ASC 815, we recognized the Tranche A 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. The change in fair value of the Tranche A Warrants resulted in a gain of $1.5 million and a loss of $0.3 million during the three months ended June 30, 2024 and 2023, respectively; and a gain of $0.3 million and a loss of $0.3 million during the six months ended June 30, 2024 and 2023, respectively. We estimate the fair value using a Black-Scholes option-pricing model with probability weights for the occurrence of the following events: (i) FDA acceptance of an NDA for CNM-Au8, (ii) settlement upon a fundamental transaction, (iii) dissolution of the Company, and (iv) another outcome outside of (i)-(iii). These estimates require significant judgment. As of June 30, 2024 and December 31, 2023, the unobservable inputs were as follows:

	June 30, 2024	December 31, 2023
Expected stock price volatility	91.90% –103.70%	100.00% –110.00%
Risk-free interest rate	4.70% –5.20%	4.13% –4.74%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	0.75 –1.96	1.08 –2.46
Probability of NDA acceptance	30.00%	20.00%
Probability of fundamental transaction	10.00%	25.00%
Probability of dissolution	55.00%	50.00%
Probability of other outcome	5.00%	5.00%

Income Taxes

We account for uncertainty in income taxes by applying a two-step process to determine the amount of tax benefit to be recognized in the condensed consolidated financial statements. First, the tax position is evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. Additionally, we assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. 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 inputs include the expected price volatility, risk-free interest rate, expected dividend yield, and expected term. For the six months ended June 30, 2024 and 2023, the unobservable inputs were as follows:

	Six Months Ended June 30,	
	2024	2023
Expected stock price volatility	97.78% –110.82%	96.22% –103.24%
Risk-free interest rate	4.04% –4.58%	3.26% –4.17%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 –10.00	5.00 –6.43

We estimate the fair value of restricted stock awards using a Monte Carlo valuation model to simulate the achievement of certain stock price milestones. The unobservable inputs include the expected stock price volatility, risk-free interest rate, and expected term. No restricted stock awards were granted during the six months ended June 30, 2024 and 2023.

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, 2024, 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, 2024, 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 on Form 10-Q 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 United States 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 Securities and Exchange Commission (the "SEC") 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, 2023 and 2022, 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 2023, we made the following enhancements to our control environment:

- we have continued to strengthen 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 have 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 2024. 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*, there were no changes in our internal control over financial reporting during the quarter ended June 30, 2024, 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 2023 Annual Report on Form 10-K which was filed with the SEC on March 13, 2024. There have been no material changes to the risk factors since previously disclosed in the 2023 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, 2024, 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
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#	Clene Inc. Amended 2020 Stock Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on May 30, 2024).
10.2	Amended and Restated Exclusive Supply Agreement, dated April 25, 2024, between Clene Nanomedicine, Inc. and 4Life Research, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on April 26, 2024).
10.3	Amended and Restated License Agreement, dated April 25, 2024, between Clene Nanomedicine, Inc. and 4Life Research, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant on April 26, 2024).
10.4	FDP Cost Reimbursement Subaward, dated April 3, 2024, by and between Clene Nanomedicine, Inc. and the Trustees of Colombia University in the City of New York (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on April 9, 2024).
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.
# Management contract or compensatory plan or agreement

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 7, 2024

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

Dated: August 7, 2024

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

Exhibit 31.1

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 7, 2024

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

Exhibit 31.2

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 7, 2024

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

Exhibit 32.1

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, 2024, 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 7, 2024

/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.

Exhibit 32.2

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, 2024, 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 7, 2024

/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.