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, 2023

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-half of one share of Common Stock for $11.50 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 10, 2023 was 128,404,735.

CLENE INC.
Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2023

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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 49,243	$ 18,332
Marketable securities	—	4,983
Accounts receivable	161	189
Inventory	52	43
Prepaid expenses and other current assets	3,915	5,648
Total current assets	53,371	29,195
Restricted cash	58	58
Operating lease right-of-use assets	4,383	4,602
Property and equipment, net	10,033	10,638
TOTAL ASSETS	$ 67,845	$ 44,493
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 846	$ 3,014
Accrued liabilities	4,298	3,863
Operating lease obligations, current portion	529	488
Finance lease obligations, current portion	62	74
Notes payable, current portion	—	6,418
Total current liabilities	5,735	13,857
Operating lease obligations, net of current portion	5,235	5,557
Finance lease obligations, net of current portion	—	34
Notes payable, net of current portion	16,017	9,483
Convertible notes payable	9,822	9,770
Common stock warrant liabilities	8,201	—
Clene Nanomedicine contingent earn-out liability	1,154	2,264
Initial Stockholders contingent earn-out liability	148	291
TOTAL LIABILITIES	46,312	41,256
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.0001 par value: 300,000,000 and 150,000,000 shares authorized at June 30, 2023 and December 31, 2022, respectively; 128,401,112 and 74,759,591 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	13	7
Additional paid-in capital	251,478	196,246
Accumulated deficit	(230,132)	(193,219)
Accumulated other comprehensive income	174	203
TOTAL STOCKHOLDERS' EQUITY	21,533	3,237
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 67,845	$ 44,493

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, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Revenue:				
Product revenue	$ 226	$ 2	$ 290	$ 9
Royalty revenue	43	33	86	56
Total revenue	269	35	376	65
Operating expenses:				
Cost of revenue	66	—	71	—
Research and development	6,615	9,166	14,010	17,746
General and administrative	3,924	4,464	7,363	9,250
Total operating expenses	10,605	13,630	21,444	26,996
Loss from operations	(10,336)	(13,595)	(21,068)	(26,931)
Other income (expense), net:				
Interest income	213	61	385	85
Interest expense	(1,104)	(751)	(2,170)	(1,533)
Gain on termination of lease	—	—	—	420
Commitment share expense	(3)	—	(402)	—
Issuance costs for common stock warrant liability	(333)	—	(333)	—
Loss on initial issuance of equity	(14,840)	—	(14,840)	—
Change in fair value of common stock warrant liabilities	(383)	20	(383)	2
Change in fair value of Clene Nanomedicine contingent earn-out liability	1,165	8,310	1,110	8,253
Change in fair value of Initial Stockholders contingent earn-out liability	150	1,066	143	1,054
Research and development tax credits and unrestricted grants	341	356	655	655
Other income (expense), net	(13)	(1)	(10)	107
Total other income (expense), net	(14,807)	9,061	(15,845)	9,043
Net loss before income taxes	(25,143)	(4,534)	(36,913)	(17,888)
Income tax benefit	—	—	—	—
Net loss	(25,143)	(4,534)	(36,913)	(17,888)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	6	(37)	20	(87)
Foreign currency translation adjustments	(53)	(110)	(49)	(60)
Total other comprehensive loss	(47)	(147)	(29)	(147)
Comprehensive loss	$ (25,190)	$ (4,681)	$ (36,942)	$ (18,035)
Net loss per share – basic and diluted	$ (0.29)	$ (0.07)	$ (0.46)	$ (0.28)
Weighted average common shares used to compute basic and diluted net loss per share	86,050,405	63,335,271	81,077,661	63,095,400

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, 2022	74,759,591	$ 7	$ 196,246	$ (193,219)	$ 203	$ 3,237
Issuance of common stock	3,227,758	1	4,664	—	—	4,665
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	77,987,349	$ 8	$ 203,133	$ (204,989)	$ 221	$ (1,627)
Issuance of common stock	50,402,893	5	40,924	—	—	40,929
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	10,870	—	—	—	—	—
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	128,401,112	$ 13	$ 251,478	$ (230,132)	$ 174	$ 21,533
Balances at December 31, 2021	62,312,097	6	175,659	(163,301)	233	12,597
Reclassification of common stock warrant liability to equity	—	—	305	—	—	305
Exercise of stock options	934,448	—	267	—	—	267
Stock-based compensation expense	—	—	2,202	—	—	2,202
Unrealized loss on available-for-sale securities	—	—	—	—	(50)	(50)
Foreign currency translation adjustment	—	—	—	—	50	50
Net loss	—	—	—	(13,354)	—	(13,354)
Balances at March 31, 2022	63,246,545	$ 6	$ 178,433	$ (176,655)	$ 233	$ 2,017
Exercise of stock options	110,000	—	17	—	—	17
Stock-based compensation expense	—	—	2,184	—	—	2,184
Issuance of common stock upon vesting of restricted stock awards	65,363	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	—	(37)	(37)
Offering costs	—	—	(100)	—	—	(100)
Foreign currency translation adjustment	—	—	—	—	(110)	(110)
Net loss	—	—	—	(4,534)	—	(4,534)
Balances at June 30, 2022	63,421,908	$ 6	$ 180,534	$ (181,189)	$ 86	$ (563)

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, 2023	2022
Cash flows from operating activities:		
Net loss	$ (36,913)	$ (17,888)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	844	482
Non-cash lease expense	219	183
Commitment share expense	402	—
Issuance costs for common stock warrant liability	333	—
Loss on initial issuance of equity	14,840	—
Change in fair value of common stock warrant liabilities	383	(2)
Change in fair value of Clene Nanomedicine contingent earn-out liability	(1,110)	(8,253)
Change in fair value of Initial Stockholders contingent earn-out liability	(143)	(1,054)
Stock-based compensation expense	4,674	4,386
Gain on termination of lease	—	(420)
Accretion of debt discount	508	442
Non-cash interest expense	186	72
Changes in operating assets and liabilities:		
Accounts receivable	28	49
Inventory	(9)	(66)
Prepaid expenses and other current assets	1,733	(989)
Accounts payable	(2,168)	1,528
Accrued liabilities	235	(1,044)
Operating lease obligations	(281)	(240)
Net cash used in operating activities	(16,239)	(22,814)
Cash flows from investing activities:		
Purchases of marketable securities	—	(24,549)
Proceeds from maturities of marketable securities	5,000	2,500
Proceeds from sales of marketable securities	—	3,016
Purchases of property and equipment	(239)	(1,824)
Net cash provided by (used in) investing activities	4,761	(20,857)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	284
Proceeds from issuance of common stock and warrants, net of offering costs	42,114	—
Payments of finance lease obligations	(46)	(65)
Proceeds from the issuance of notes payable	350	694
Payments of notes payable issuance costs	—	(30)
Payment of deferred offering costs	—	(100)
Net cash provided by financing activities	42,418	783
Effect of foreign exchange rate changes on cash and restricted cash	(29)	(147)
Net increase (decrease) in cash, cash equivalents and restricted cash	30,911	(43,035)
Cash, cash equivalents and restricted cash – beginning of period	18,390	50,346
Cash, cash equivalents and restricted cash – end of period	$ 49,301	$ 7,311
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	49,243	7,253
Restricted cash	58	58
Cash, cash equivalents and restricted cash	$ 49,301	$ 7,311
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	$ —
Lease liability arising from obtaining right-of-use assets, leasehold improvements, and lease incentives	$ —	$ 2,343
Lease incentive realized	$ —	$ 500
Lease liability settled through termination of lease	$ —	$ 602
Reclassification of common stock warrant liability to permanent equity	$ —	$ 305
Purchases of property and equipment in accounts payable	$ —	$ 1,075
Supplemental cash flow information:		
Cash paid for interest expense	$ 1,985	$ 1,013

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"), a 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 $10.3 million and $13.6 million for the three months ended June 30, 2023 and 2022, respectively; and $21.1 million and $26.9 million for the six months ended June 30, 2023 and 2022, respectively. Our accumulated deficit was $230.1 million and $193.2 million as of June 30, 2023 and December 31, 2022, respectively. Our cash, cash equivalents, and marketable securities totaled $49.2 million and $23.3 million as of June 30, 2023 and December 31, 2022, respectively, and net cash used in operating activities was $16.2 million and $22.8 million for the six months ended June 30, 2023 and 2022, 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 and equity purchase agreement and potential proceeds from the exercise of outstanding warrants. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the three months ended June 30, 2023, we raised approximately $37.4 million of net proceeds in an underwritten public equity offering. We have implemented cost-saving initiatives, including delaying and reducing research and development programs and commercialization efforts, reduction in executive compensation, a hiring freeze, 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.

Impact of the COVID-19 Pandemic

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic, including the resurgence of cases relating to the spread of new variants, on our business and operations is highly uncertain and difficult to predict, as the responses that we, other businesses, and governments are taking continue to evolve. Government measures taken in response to the COVID-19 pandemic have had a significant impact, both direct and indirect, on businesses, commerce, and economies worldwide, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The COVID-19 pandemic may affect our ability to initiate and complete preclinical studies and clinical trials, delay the initiation of future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In particular, we and our third-party contract research organizations ("CROs") have faced disruptions that affected our ability to initiate and complete preclinical studies, caused manufacturing disruptions, and created delays at clinical trial site initiation and clinical trial enrollment, which ultimately led to the early conclusion of a clinical trial.

We are monitoring the potential impact of the COVID-19 pandemic on our business, financial condition, results of operations, and cash flows. While the COVID-19 pandemic has led to various research restrictions and led to pauses and early conclusion of one of our clinical trials, these impacts have been temporary and to date we have not experienced material business disruptions or incurred impairment losses in the carrying values of our assets as a result of the COVID-19 pandemic. We are not aware of any specific related event or circumstance that would require us to revise the estimates reflected in our condensed consolidated financial statements. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, financial condition, results of operations, and cash flows, including planned future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

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, 2023 and 2022 are unaudited.

Results of operations for the three and six months ended June 30, 2023 and 2022 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, 2023 and 2022 should be read in conjunction with the audited consolidated financial statements included in our Annual Report on Form 10-K.

Use of Estimates

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

Risks and Uncertainties

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.

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 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.

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 $38,000 in raw materials and $14,000 in finished goods as of June 30, 2023, and $29,000 in raw material and $14,000 in finished goods as of December 31, 2022. Inventory relates to our Supplements segment.

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 3-5 years for laboratory equipment, 3-7 years for furniture and fixtures, and 2-5 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.

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, and we account for a convertible preferred stock as a single equity instrument measured at its historical 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 of 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. We recognize lease expense for these short-term leases on a straight-line basis over the lease term in the condensed consolidated statements of operations and comprehensive loss.

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. In the condensed consolidated statements of operations and comprehensive loss, 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 of Clene Nanomedicine's stockholders are entitled to receive additional shares (the "Clene Nanomedicine Contingent Earn-out") of Common Stock as follows: (i) 3,338,483 shares of Common Stock if (a) the volume-weighted average price ("VWAP") of our Common Stock equals or exceeds $15.00 (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) 2,503,851 shares of Common Stock if (a) the VWAP of our Common Stock equals or exceeds $20.00 (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 an additional issuance equal to Milestone 1. Tottenham's former officers and 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) 375,000 shares of Common Stock upon the achievement of Milestone 1; and (ii) 375,000 shares of Common Stock upon achievement of Milestone 2. If Milestone 1 is not achieved but Milestone 2 is achieved, the Initial Stockholders will receive an additional issuance 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-classified instruments or liability-classified instruments based on an assessment of the warrant terms and applicable authoritative guidance. 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 of 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 the condensed consolidated balance sheets 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 condensed consolidated statements of operations and comprehensive loss 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 in the condensed consolidated balance sheets if the conditions or performance obligations are expected to be met within the next twelve months. We recognized grant funding of $0.1 million and $0.1 million as a reduction of research and development expenses during the three and six months ended June 30, 2023, respectively. We did not fulfill any grant conditions or performance obligations during the three and six months ended June 30, 2022.

Foreign Currency Translation and Transactions

Our functional currency is the U.S. dollar. Clene Australia determined its functional currency to be the Australian dollar and Clene Netherlands determined its functional currency to be the Euro. We use the U.S. dollar as our reporting currency for the condensed consolidated financial statements. The results of our non-U.S. dollar based functional currency operations are translated to U.S. dollars at the average exchange rates during the period. Our assets and liabilities are translated using the current exchange rate as of the balance sheet date and stockholders' equity is translated using historical rates.

Adjustments resulting from the translation of the condensed consolidated financial statements of our foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' equity. 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 that result from transactions and economic events other than those with stockholders. The only elements of other comprehensive loss in any periods presented were translation of foreign currency denominated balances of Clene Australia and Clene Netherlands to U.S. dollars for consolidation and unrealized gain (loss) on available-for-sale securities.

Segment Information

We have determined that our chief executive officer is the chief operating decision maker ("CODM"). Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the CODM in making decisions regarding resource allocation and assessing performance. We view our operations and manage our business in two operating segments, which are our reportable segments: (1) the development and commercialization of novel clean-surfaced nanotechnology therapeutics ("Drugs"), and (2) the development and commercialization of dietary supplements ("Supplements").

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 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.

Note 3. Marketable Securities

Available-for-Sale Securities

We had no available-for-sale securities as of June 30, 2023. Available-for-sale securities as of December 31, 2022 were as follows:

	December 31, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 3,496	$ —	$ (14)	$ 3,482
Corporate debt securities	1,501	—	—	1,501
Total	$ 4,997	$ —	$ (14)	$ 4,983

Proceeds from the sale and maturity of available-for-sale securities were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2023	2022	2023	2022
Proceeds from maturities of marketable securities	$ 5,000	$ 2,500	$ 5,000	$ 2,500
Proceeds from sales of marketable securities	—	3,016	—	3,016
Total	$ 5,000	$ 5,516	$ 5,000	$ 5,516

Realized gains and losses included in earnings from the sale of available-for-sale securities were insignificant. As of December 31, 2022, 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, 2023 and December 31, 2022 were as follows:

(in thousands)	June 30, 2023	December 31, 2022
Research and development tax credits receivable	$ 858	$ 2,777
Metals to be used in research and development	2,174	2,290
Other	883	581
Total prepaid expenses and other current assets	$ 3,915	$ 5,648

Note 5. Property and Equipment, Net

Property and equipment, net, as of June 30, 2023 and December 31, 2022 were as follows:

(in thousands)	June 30, 2023	December 31, 2022
Lab equipment	$ 3,933	$ 3,934
Office equipment	178	177
Computer software	459	459
Leasehold improvements	9,983	5,677
Construction in progress	1,582	5,664
	16,135	15,911
Less accumulated depreciation	(6,102)	(5,273)
Total property and equipment, net	$ 10,033	$ 10,638

Depreciation expense recorded in research and development expense and general and administrative expense for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2023	2022	2023	2022
General and administrative	$ 67	$ 67	$ 134	$ 96
Research and development	375	220	710	386
Total depreciation expense	$ 442	$ 287	$ 844	$ 482

Note 6. Accrued Liabilities

Accrued liabilities as of June 30, 2023 and December 31, 2022 were as follows:

(in thousands)	June 30, 2023	December 31, 2022
Accrued compensation and benefits	$ 1,039	$ 2,007
Accrued CRO and clinical fees	2,716	1,297
Other	543	559
Total accrued liabilities	$ 4,298	$ 3,863

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.

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, which replaced a previous lease for the same facility and resulted a gain on termination of $0.4 million for the year ended December 31, 2022; 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, 2023 and December 31, 2022, our operating lease obligations had a weighted-average discount rate of 9.6% and 9.6%, respectively; and a weighted-average remaining term of 6.8 years and 7.3 years, respectively.

Finance Leases

Assets recorded under finance lease obligations and included in property and equipment as of June 30, 2023 and December 31, 2022 were as follows:

(in thousands)	June 30, 2023	December 31, 2022
Lab equipment	$ 408	$ 408
Work in process	228	228
Total	636	636
Less accumulated depreciation	(367)	(326)
Net	$ 269	$ 310

As of June 30, 2023 and December 31, 2022, our finance lease obligations had a weighted-average interest rate of 10.9% and 10.2%, respectively; and a weighted-average remaining term of 0.9 years and 1.2 years, respectively.

Maturity Analysis of Leases

The maturity analysis of our finance and operating leases as of June 30, 2023 was as follows:

(in thousands)	Finance Leases	Operating Leases
2023 (remainder)	$ 37	$ 481
2024	27	1,172
2025	—	1,202
2026	—	1,231
2027	—	1,129
2028	—	1,092
Thereafter	—	1,694
Total undiscounted cash flows	64	8,001
Less amount representing interest/discounting	(2)	(2,237)
Present value of future lease payments	62	5,764
Less lease obligations, current portion	(62)	(529)
Lease obligations, long term portion	$ —	$ 5,235

We expect that, in the normal course of business, the existing leases will be renewed or replaced by similar leases.

Components of Lease Cost

The components of finance and operating lease costs for the three and six months ended June 30, 2023 and 2022 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2023	2022	2023	2022
Finance lease costs:				
Amortization	$ 21	$ 21	$ 41	$ 41
Interest on lease liabilities	3	1	9	6
Operating lease costs	251	209	504	439
Short-term lease costs	2	—	2	—
Variable lease costs	72	108	122	173
Total lease costs	$ 349	$ 339	$ 678	$ 659

Supplemental Cash Flow Information

(in thousands)	Six Months Ended June 30, 2023	2022
Operating cash flows from operating leases	$ (628)	$ (612)
Operating cash flows from finance leases	$ (9)	$ (6)
Financing cash flows from finance leases	$ (46)	$ (65)

Note 8. Notes Payable and Convertible Notes Payable

Our notes payable and convertible notes payable as of June 30, 2023 and December 31, 2022 was as follows:

(in thousands, except interest rates)	Stated Interest Rate	June 30, 2023	December 31, 2022
Notes payable			
Advance Cecil, Inc. (commenced April 2019)	8.00%	$ 134	$ 130
Maryland DHCD (commenced February 2019)	8.00%	674	654
Maryland DHCD (commenced May 2022)	6.00%	1,033	682
Avenue Venture Opportunities Fund, L.P. (commenced May 2021)	14.85%	15,000	15,000
		16,841	16,466
Accrued and unpaid interest		50	22
Less unamortized discount and debt issuance costs		(874)	(587)
Less notes payable, current portion, net of unamortized discount and debt issuance costs		—	(6,418)
Total notes payable, net of current portion		$ 16,017	$ 9,483
Convertible notes payable			
Avenue Venture Opportunities Fund, L.P. (commenced May 2021)	14.85%	$ 5,000	$ 5,000
Maryland DHCD (commenced December 2022)	6.00%	5,000	5,000
		10,000	10,000
Accrued and unpaid interest		157	7
Less unamortized discount and debt issuance costs		(335)	(237)
Total convertible notes payable		$ 9,822	$ 9,770

Maryland DHCD Loans

In February 2019, we entered into a loan agreement (the “2019 MD Loan”) with the Department of Housing and Community Development (“DHCD”), a principal department of the State of Maryland, for a term loan of $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 common or preferred stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. We are not in violation of any covenants. The 2019 MD Loan established “Phantom Shares” based on 119,907 shares of Common Stock. Repayment of the full balance is due on February 22, 2034, with the repayment amount and carrying value 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 at the end of each reporting period. As of June 30, 2023 and December 31, 2022, 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 for the three months ended June 30, 2023 and 2022, respectively; and interest expense of $20,000 and $20,000 for the six months ended June 30, 2023 and 2022, respectively.

In May 2022, we entered into a loan agreement (the “2022 MD Loan”) with DHCD, which provides for a term loan of up to $3.0 million bearing simple interest at an annual rate of 6.00% for the purchase of certain personal property (the “Assets”) related to our production activities. As of June 30, 2023, we had drawn $1.0 million under the term loan, with the remainder available for future Asset purchases until May 17, 2024. The first twelve payments, commencing July 1, 2022, are deferred, followed by eighteen monthly installments of interest-only based on the amount advanced under the loan, each up to a maximum amount of $15,000; followed by monthly installments of principal and interest in the amount of $33,306, payable for the lesser of thirty months or until the principal and accrued and unpaid interest is fully repaid, with a balloon payment of all remaining principal and accrued and unpaid interest due on the maturity date of July 1, 2027. We incurred $31,000 of debt issuance costs which were recorded as a debt discount. Under a priority of liens agreement by and between DHCD and Avenue, an existing secured creditor of the Company, DHCD was granted a continuing security interest in the Assets as collateral which shall be a first priority lien. We recognized interest expense of $16,000 and $2,000 for the three months ended June 30, 2023 and 2022, respectively; and interest expense of $28,000 and $2,000 for the six months ended June 30, 2023 and 2022, respectively.

In December 2022, we entered into a loan agreement (the “2022 DHCD Loan”) with DHCD for a term loan of $5.0 million bearing simple interest at an annual rate of 6.00%. The first twelve payments, commencing January 1, 2023, are deferred, followed by 48 monthly installments of interest-only, with a balloon payment of all principal and accrued and unpaid interest due on the maturity date of January 1, 2028. We incurred $0.1 million of debt issuance costs which were recorded as a debt discount. At any time after December 8, 2023, DHCD may, in its sole discretion, convert any portion of the outstanding 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, ending on and including the conversion date; or (ii) $4.00 per share (the “DHCD Conversion Feature”). The DHCD Conversion Feature did not meet the requirements for derivative accounting. For the three and six months ended June 30, 2023, we recognized (i) total interest expense of $0.1 million and $0.2 million, respectively; (ii) coupon interest expense of $0.1 million and $0.2 million, respectively; and (iii) amortization of debt issuance costs of $0 and ($2,000), respectively; and the effective interest rate was 5.91%.

Cecil County Loan

In April 2019, we entered into a loan agreement (the “2019 Cecil Loan”) with Advance Cecil Inc., a non-stock corporation formed under the laws of the state of Maryland, for a term loan of $0.1 million bearing simple interest at an annual rate of 8.00%. The 2019 Cecil Loan established “Phantom Shares” based on 23,981 shares of Common Stock. Repayment of the full balance is due on April 30, 2034, with the repayment amount and carrying value 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 at the end of each reporting period. As of June 30, 2023 and December 31, 2022, 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 for the three months ended June 30, 2023 and 2022, respectively; and interest expense of $4,000 and $4,000 for the six months ended June 30, 2023 and 2022, respectively.

Avenue Loan

In May 2021, we entered into a loan agreement (the “2021 Avenue Loan”) with Avenue for a term loan of 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, 2023 and December 31, 2022, the interest rate was 14.85% and 14.10%, respectively. The first tranche consisted of $15.0 million funded in May 2021 plus $5.0 million funded in September 2021 (“Tranche 1”). The remaining unfunded $10.0 million (“Tranche 2”) was not drawn and expired on December 31, 2022. Payments were interest-only for the first twelve months and the interest-only period was extended (i) twelve months due to our achievement of a statistically significant result in certain clinical trials, plus (ii) an additional twelve months (through June 30, 2024), pursuant to an amendment to the 2021 Avenue Loan 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 equity offering in June 2023 (“Equity Milestone 1”). The interest-only period may be extended through December 31, 2024, subject to (a) our receipt of net proceeds of at least $40.0 million, in addition to Equity Milestone 1, from the sale and issuance of our equity securities on or before June 30, 2024 (“Equity Milestone 2”) and (b) receipt by Avenue of reasonably satisfactory evidence that the U.S. Food and Drug Administration (“FDA”) has accepted a New Drug Application (“NDA”) filed by us for the treatment of amyotrophic lateral sclerosis (the “ALS NDA Milestone”). Following the interest-only period, we are required to make equal monthly installments of principal plus interest at the variable rate then in effect until the end of the 42-month term on December 1, 2024, which may be extended from December 1, 2024 to December 1, 2025 so long as no event of default has occurred and is continuing and we have achieved (i) Equity Milestone 2 and (ii) the ALS NDA Milestone. 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. We incurred $0.8 million of debt issuance costs of which $47,000 was expensed immediately and the remainder was recorded as a debt discount.

At any time between May 21, 2022 and May 21, 2024, Avenue may, in its sole discretion, convert up to $5.0 million of outstanding principal into Common Stock at a price per share equal to $10.36 (the “Avenue Conversion Feature”), subject to certain minimum price and volume restrictions related to our Common Stock on Nasdaq. The Final Payment and Avenue Conversion Feature did not meet the requirements for derivative accounting. As of June 30, 2023 and December 31, 2022, unamortized debt discount and issuance costs related to the convertible note were $0.3 million and $0.2 million, respectively. For the convertible note for the three months ended June 30, 2023 and 2022, we recognized (i) total interest expense of $0.3 million and $0.2 million, respectively; (ii) coupon interest expense of $0.2 million and $0.1 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 22.55% and 16.95%, respectively. For the six months ended June 30, 2023 and 2022, we recognized (i) total interest expense of $0.5 million and $0.4 million, respectively; (ii) coupon interest expense of $0.4 million and $0.3 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 22.55% and 16.95%, respectively.

We are subject to covenants until maturity, including limitations on our ability to retire, repurchase, or redeem our Common Stock, options, and warrants other than per the terms of the securities; limitations on our ability to pay dividends of cash or property; 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. Under the 2021 Avenue Loan, Avenue also 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 of 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 $1.0 million and $0.7 million for the three months ended June 30, 2023 and 2022, respectively; and interest expense of $2.0 million and $1.5 million for the six months ended June 30, 2023 and 2022, respectively.

At inception of the 2021 Avenue Loan, we issued to Avenue a warrant to purchase Common Stock based on the amount of funded principal, equal to 115,851 shares of Common Stock at an exercise price of $8.63 per share (the "Original Avenue Warrant"). A portion of net proceeds from the issuance of the 2021 Avenue Loan were allocated to the Avenue Warrant in an amount equal to its fair value of $0.7 million, which was recorded as a debt discount. Pursuant to the Second Amendment, the Original Avenue Warrant was cancelled and terminated, and a new warrant to purchase 3,000,000 shares of Common Stock at $0.80 per share was issued (the "New Avenue Warrant"). Avenue may exercise the New Avenue Warrant by making a cash payment equal to the exercise price multiplied by the number of shares or on a net or "cashless" basis. In the event of certain transactions which constitute 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 (cash or otherwise) 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 principal payments, net of unamortized discounts, 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
2023 (remainder)	$ —	$ —	$ —	$ —	$ —
2024	—	—	20,000	—	—
2025	—	—	—	347	—
2026	—	—	—	369	—
2027	—	—	—	317	—
2028	—	—	—	—	5,000
Thereafter	674	134	—	—	—
Subtotal of future principal payments	674	134	20,000	1,033	5,000
Accrued and unpaid interest	—	—	—	50	157
Less unamortized discount and debt issuance costs	—	—	(1,133)	(24)	(52)
Total	$ 674	$ 134	$ 18,867	$ 1,059	$ 5,105

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, 2023 and December 31, 2022, we had commitments under various agreements for capital expenditures totaling $0.4 million and $1.6 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.

In September 2019, we received grant funding of $0.3 million from the National Multiple Sclerosis Society ("NMSS") to fund biomarker research related our VISIONARY-MS Phase 2 clinical trial. Pursuant to a Sponsored Research Agreement with NMSS, if we make future commercial sales of CNM-Au8 for the treatment of MS, we agreed to repay certain amounts based upon the following milestones: (i) 50% of the grant upon the first commercial product sale, (ii) an additional 50% of the grant upon cumulative sales of $10.0 million, (iii) an additional 150% of the grant upon cumulative sales of $50.0 million, and (iv) an additional 200% of the grant upon cumulative sales of $100.0 million, with the maximum repayment equal to 450% of the grant funding if all milestones are achieved. Additionally, if NMSS has not yet received repayments equal in the aggregate to 300% of the grant funding, then upon the closing of any of the following events we will repay 300% of the grant funding, or $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 biomarker 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, or (v) a collaboration with a third-party to develop CNM-Au8 for the treatment of MS. As of June 30, 2023, we have not met any of the above milestones and the biomarker research has not been completed. We accounted for this contingency in accordance with ASC 450, *Contingencies* ("ASC 450"). Management has assessed the likelihood of occurrence of each contingent event as less than probable and therefore no contingent liability is recognized in the condensed consolidated balance sheets. Management's estimate of the possible range of loss is between the minimum and maximum repayment amounts, equal to 50% and 450% of the grant funding, or approximately $0.2 million and $1.5 million, respectively. However, it is at least reasonably possible that Management's estimate of the probability of occurrence of each contingent event and the possible range of loss will change in the near term.

In May 2023, we received grant funding of $0.7 million from NMSS to fund brain target engagement research related to our REPAIR-MS and REPAIR-PD Phase 2 clinical trials. Pursuant to a Sponsored Research Agreement with NMSS, if we make future commercial sales of CNM-Au8 for the treatment of MS, we agreed to repay certain amounts based upon the following milestones: (i) 50% of the grant upon the first commercial product sale, (ii) an additional 50% of the grant upon cumulative sales of $10.0 million, (iii) an additional 150% of the grant upon cumulative sales of $50.0 million, and (iv) an additional 200% of the grant upon cumulative sales of $100.0 million, with the maximum repayment equal to 450% of the grant funding if all milestones are achieved. Additionally, if NMSS has not yet received repayments equal in the aggregate to 150% of the grant funding, then upon the closing of any of the following events we will repay 150% of the grant funding, or $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 biomarker 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, or (v) licensing of our commercialization rights to CNM-Au8 for the treatment of MS. As of June 30, 2023, we have not met any of the above milestones and the biomarker research has not been completed. We accounted for this contingency in accordance with ASC 450, *Contingencies*. Management has assessed the likelihood of occurrence of each contingent event as less than probable and therefore no contingent liability is recognized in the condensed consolidated balance sheets. Management's estimate of the possible range of loss is between the minimum and maximum repayment amounts, equal to 50% and 450% of the grant funding, or approximately $0.3 million and $3.0 million, respectively. However, it is at least reasonably possible that Management's estimate of the probability of occurrence 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, 2023 and 2022 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
United States	$ (24,856)	$ (3,398)	$ (36,402)	$ (16,355)
Foreign	(287)	(1,136)	(511)	(1,533)
Net loss before income taxes	$ (25,143)	$ (4,534)	$ (36,913)	$ (17,888)

We are subject to taxation in the U.S., Australia, Netherlands, and various state jurisdictions. Our tax returns from 2016 to present are subject to examination by 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 for the three months ended June 30, 2023 and 2022, respectively; and $0.1 million and $0.1 million for the six months ended June 30, 2023 and 2022, respectively.

Stock Compensation Plans

The Clene Nanomedicine, Inc. 2014 Stock Plan ("the 2014 Stock Plan") was adopted in July 2014. Effective as of the closing of the Reverse Recapitalization, no additional awards may be granted under the 2014 Stock Plan. As of June 30, 2023, 5,363,628 stock options remained outstanding under the 2014 Stock Plan.

The Clene Inc. 2020 Amended Stock Plan (the "2020 Stock Plan") was adopted in December 2020 and amended in May 2023 and 18,400,000 shares of Common Stock are reserved for issuance thereunder. As of June 30, 2023, a total of 16,958,548 stock options and other stock awards had been granted under the 2020 Stock Plan, and 1,441,452 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 for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
General and administrative	$ 1,327	$ 1,351	$ 2,577	$ 2,809
Research and development	1,124	833	2,097	1,577
Total stock-based compensation expense	$ 2,451	$ 2,184	$ 4,674	$ 4,386

Stock-based compensation expense by award type for the three and six months ended June 30, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Stock options	$ 2,438	$ 2,184	$ 4,660	$ 4,386
Stock awards	13	—	14	—
Total stock-based compensation expense	$ 2,451	$ 2,184	$ 4,674	$ 4,386

Stock Options

Outstanding stock options and related activity for the six months ended June 30, 2023 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, 2022	15,260,297	$ 2.98	7.28	$ 2,348
Granted	6,361,362	0.97	9.93	—
Forfeited	(394,609)	5.43	—	—
Outstanding – June 30, 2023	21,227,050	$ 2.33	7.71	$ 1,879
Vested and exercisable – June 30, 2023	8,546,494	$ 2.79	5.23	$ 1,879
Vested, exercisable or expected to vest – June 30, 2023	21,227,050	$ 2.33	7.71	$ 1,879

As of June 30, 2023 and December 31, 2022, we had approximately $17.9 million and $18.2 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 2.44 years and 2.58 years, respectively.

The weighted-average grant-date fair value of stock options granted during the six months ended June 30, 2023 and 2022 was $0.77 and $2.24, respectively. The assumptions used to calculate the fair value of stock options granted during the six months ended June 30, 2023 and 2022 were as follows:

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Expected stock price volatility	96.22% – 103.24%	89.57% – 93.38%
Risk-free interest rate	3.26% – 4.17%	1.65% – 3.00%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 – 6.43	5.00 – 6.98

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 for the six months ended June 30, 2023 was as follows:

	Number of Stock Awards	Weighted Average Grant Date Fair Value
Unvested balance – December 31, 2022	769,139	$ 9.84
Granted	43,479	1.15
Converted to shares of Common Stock upon vesting	(10,870)	1.15
Forfeited	(746)	9.84
Unvested balance – June 30, 2023	801,002	$ 9.49

As of June 30, 2023, we had approximately $37,000 of unrecognized stock-based compensation costs related to non-vested stock awards which is expected to be recognized over a weighted-average period of 0.73 years. As of December 31, 2022, we had no unrecognized stock-based compensation costs related to non-vested stock awards.

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, 2023 is as follows:

	June 30, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents				
Money market funds	$ 6,455	$ —	$ —	$ 6,455
U.S. Treasury securities	—	37,729	—	37,729
Common stock warrant liabilities	—	—	8,201	8,201
Clene Nanomedicine contingent earn-out liability	—	—	1,154	1,154
Initial Stockholders contingent earn-out liability	—	—	148	148

The fair value hierarchy for financial instruments measured at fair value on a recurring basis as of December 31, 2022 is as follows:

	December 31, 2022			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents				
Money market funds	$ 14,317	$ —	$ —	$ 14,317
Marketable securities				
Commercial paper	—	3,482	—	3,482
Corporate debt securities	—	1,501	—	1,501
Clene Nanomedicine contingent earn-out liability	—	—	2,264	2,264
Initial Stockholders contingent earn-out liability	—	—	291	291

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 for 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

Changes in the fair value of our Level 3 financial instruments for the six months ended June 30, 2022 were as follows:

(in thousands)	**Common Stock Warrant Liability**	**Clene Nanomedicine Contingent Earn-out**	**Initial Stockholders Contingent Earn-out**
Balance – December 31, 2021	$ 474	$ 18,100	$ 2,317
Change in fair value	(2)	(8,253)	(1,054)
Reclassification from liability to equity	(305)	—	—
Balance – June 30, 2022	$ 167	$ 9,847	$ 1,263

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 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 Original Avenue Warrant, comprised of the Tranche 1 warrant and the contingently issuable Tranche 2 warrant to purchase shares of Common Stock, were classified as liabilities and recorded at fair value at inception of the 2021 Avenue Loan. As of March 31, 2022, the exercise price and quantity of shares for the Tranche 1 warrant became fixed and therefore qualified for equity classification. We remeasured the Tranche 1 warrant liability to fair value as of March 31, 2022 and recognized the change in fair value in the condensed consolidated statements of operations and comprehensive loss and the Tranche 1 warrant liability was reclassified to additional paid-in capital. Our ability to draw Tranche 2 expired on December 31, 2022 and the Tranche 2 warrant liability was extinguished and we recognized income of $0.2 million as of December 31, 2022.

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 our estimate of the likelihood of settlement of the instrument upon a change of control transaction and our estimate of the likelihood of dissolution of the Company, which requires 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, 2023
Expected stock price volatility	90.00% – 110.00%
Risk-free interest rate	4.13% – 5.40%
Expected dividend yield	0.00%
Expected term (in years)	0.75 – 5.00
Probability of change of control	5.00%
Probability of dissolution	60.00%
Probability of other outcome	35.00%

The Tranche A 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) 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. 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, 2023
Expected stock price volatility	100.00% – 110.00%
Risk-free interest rate	4.49% – 5.40%
Expected dividend yield	0.00%
Expected term (in years)	1.08 – 2.96
Probability of NDA acceptance	30.00%
Probability of fundamental transaction	5.00%
Probability of dissolution	60.00%
Probability of other outcome	5.00%

The Tranche B Warrant qualified for equity classification at issuance. We estimated the nonrecurring fair value measurement using a Black-Scholes option-pricing model with probability weights for the occurrence of the following events: (i) FDA approval 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. The unobservable inputs to the Black-Scholes option pricing model were as follows:

	June 30, 2023
Expected stock price volatility	100.00% – 110.00%
Risk-free interest rate	3.88% – 4.97%
Expected dividend yield	0.00%
Expected term (in years)	1.46 – 7.00
Probability of NDA approval	22.50%
Probability of fundamental transaction	5.00%
Probability of dissolution	71.50%
Probability of other outcome	1.00%

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, 2023	December 31, 2022
Expected stock price volatility	110.00%	115.00%
Risk-free interest rate	4.70%	4.20%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	2.5	3.00

Note 13. Capital Stock

As of June 30, 2023 and December 31, 2022, our amended and restated certificate of incorporation (the "Certificate") authorized us to issue 300,000,000 and 150,000,000 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, 2023 and December 31, 2022, we had 128,401,112 and 74,759,591 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, 2023 and December 31, 2022, outstanding warrants to purchase shares of Common Stock were as follows:

						Number of Shares Issuable	
Date Exercisable		**Exercise Price**	**Expiration**		**Classification**	**June 30, 2023**	**December 31, 2022**
December 2020	$	11.50	December 2025	(1)	Equity	2,407,500	2,407,500
December 2020	$	11.50	December 2025	(2)	Equity	24,583	24,583
December 2020	$	1.97	April 2023	(3)	Equity	—	1,929,111
May 2021	$	8.63	May 2026	(4)	Equity	—	115,851
June 2023	$	0.80	June 2028	(5)	Liability	3,000,000	—
June 2023	$	1.10	June 2026	(6)	Liability	50,000,000	—
June 2023	$	1.50	June 2030	(7)	Equity	50,000,000	—
Total						105,432,083	4,477,045

(1) Consists of 2,407,500 shares of Common Stock underlying warrants to purchase one-half (1/2) of one share of Common Stock, issued in connection with Tottenham's initial public offering. We may redeem the outstanding warrants, in whole and not in part, at $0.01 per warrant if the last sales price of our Common Stock equals or exceeds $16.50 per share for any twenty trading days within a thirty-trading day period. As of June 30, 2023 and December 31, 2022, no warrants had been exercised.

(2) Consists of 24,583 shares of Common Stock underlying warrants to purchase one-half (1/2) 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, 2023 and December 31, 2022, no warrants had been exercised.

(3) Consists of 1,929,111 shares of Common Stock underlying warrants to purchase one share of Common Stock, issued by Clene Nanomedicine as Series A preferred stock warrants and senior equity warrants in August 2013. As of April 2023, no warrants had been exercised and the warrants expired.

(4) Consists of 115,851 shares of Common Stock underlying the Original Avenue Warrant. As of June 2023, the warrant had not been exercised and was cancelled pursuant to an amendment to the 2021 Avenue Loan (see Note 8).

(5) Consists of 3,000,000 shares of Common Stock underlying the New Avenue Warrant, issued pursuant to an amendment to the 2021 Avenue Loan (see Note 8). As of June 30, 2023, the warrant had not been exercised.

(6) Consists of 50,000,000 shares of Common Stock underlying Tranche A Warrants to purchase one share of Common Stock, issued in our June 2023 public equity offering. As of June 30, 2023, no warrants had been exercised.

(7) Consists of 50,000,000 shares of Common Stock underlying Tranche B Warrants to purchase one share of Common Stock, issued in our June 2023 public equity offering. As of June 30, 2023, no warrants had been exercised.

Public Offerings

In October 2022, we sold 10,723,926 shares of Common Stock at a sale price of $1.01 per share to certain existing stockholders, including affiliates of our directors. The aggregate gross proceeds were $10.8 million and we paid expenses of $25,000. 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, and our prospectus supplement relating to the offering.

In June 2023, we sold 50,000,000 units at a sale price of $0.80 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 $1.10 per share (the "Tranche A Warrants"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $1.50 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 Warrants and Tranche B Warrants. We cannot predict when or if the Tranche A Warrants 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 the 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. 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 (the "ATM Agreement") with Canaccord and Oppenheimer & Co. Inc., as placement agents (the "Placement Agents"). In December 2022, we amended the ATM Agreement and removed Oppenheimer & Co. Inc. as a Placement Agent. In accordance with the terms of the ATM Agreement, we may offer and sell shares of Common Stock having an aggregate offering price of up to $50.0 million from time to time through the Placement Agent. The issuance and sale of Common Stock by us 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, and our prospectus supplement relating to the offering. On June 16, 2023, we delivered written notice to Canaccord that we were suspending and terminating the prospectus supplement (the "ATM Prospectus Supplement") related to our Common Stock issuable pursuant to the ATM Agreement. We will not make any further sales of our securities pursuant to the ATM Agreement, unless and until a new prospectus supplement is filed. Other than the termination and suspension of the ATM Prospectus Supplement, the ATM Agreement remains in full force and effect.

Subject to terms of the ATM Agreement, the Placement Agent is not required to sell any specific number or dollar amount of Common Stock but will act as our placement agent, using commercially reasonable efforts to sell, on our behalf, all of the Common Stock requested by us to be sold, consistent with the Placement Agent's normal trading and sales practices, on terms mutually agreed between the Placement Agent and us. The Placement Agent will be entitled to compensation under the terms of the ATM Agreement at a fixed commission rate of 3.0% of the gross proceeds from each issuance and sale of Common Stock, if any. During the three and six months ended June 30, 2023, we sold 0 and 2,895,090 shares of Common Stock under the ATM Agreement, 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, and our prospectus supplement relating to the transaction. On June 16, 2023, we delivered written notice to Lincoln Park that we were terminating the prospectus supplement (the "Purchase Agreement Prospectus Supplement") and the offering with respect to our 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 75,000 shares of Common Stock (a "Regular Purchase"), which may be increased up to (i) 100,000 shares if the closing price of our Common Stock is not below $1.00, (ii) 150,000 shares if the closing price of our Common Stock is not below $2.00, and (iii) 200,000 shares if the closing price of our Common Stock is not below $4.00. 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 332,668 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 166,334 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 15,310,115 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 $1.2404. 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, 2023. During the three and six months ended June 30, 2023, we sold 400,000 shares of Common Stock under the Purchase Agreement, issued 2,893 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, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except share and per share data)	**2023**	**2022**	**2023**	**2022**
Numerator:				
Net loss attributable to common stockholders	$ (25,143)	$ (4,534)	$ (36,913)	$ (17,888)
Denominator:				
Weighted average common shares outstanding	86,050,405	63,335,271	81,077,661	63,095,400
Net loss per share attributable to common stockholders – basic and diluted	$ (0.29)	$ (0.07)	$ (0.46)	$ (0.28)

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, 2023 and 2022 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,	
	2023	**2022**	**2023**	**2022**
Convertible notes payable (see Note 8)	1,732,703	482,703	1,732,703	482,703
Common stock warrants (see Note 13)	105,432,083	4,477,045	105,432,083	4,477,045
Options to purchase common stock (see Note 11)	21,227,050	12,071,276	21,227,050	12,071,276
Unvested restricted stock awards (see Note 11)	801,002	849,215	801,002	849,215
Contingent earn-out shares (see Note 2)	6,592,334	6,592,334	6,592,334	6,592,334
Total	135,785,172	24,472,573	135,785,172	24,472,573

Note 15. Related Party Transactions

License and Supply Agreements

In August 2018, we entered into a license agreement and exclusive supply agreement (collectively, the "4Life Agreement") in conjunction with 4Life's investment in our Series C preferred stock and warrants. Pursuant to the 4Life Agreement, we granted 4Life an exclusive license to sell certain dietary supplements. The term of the exclusive license is five years from the commencement of product sales under the 4Life Agreement, which was in April 2021, with options to renew for additional five-year terms. We provide non-pharmaceutical product to 4Life for development, and 4Life pays royalties of 3% of incremental sales. 4Life is subject to an annual minimum sales requirement. If the minimum sales are unmet, 4Life may pay us an additional fee to maintain exclusivity or have the license converted to non-exclusive.

Total revenue under the 4Life Agreement for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Product revenue from related parties	$ 193	$ —	$ 256	$ —
Royalty revenue from related parties	43	33	86	56
Total revenue from related parties	$ 236	$ 33	$ 342	$ 56

Note 16. Segment Information

Our operating segment profit measure is segment loss from operations, which is calculated as revenue less cost of revenue, research and development, and general and administrative expenses. Profit and loss information by reportable segment for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Drugs:				
Revenue from external customers	$ —	$ —	$ —	$ —
Loss from operations	(10,525)	(13,596)	(21,323)	(26,939)
Supplements:				
Revenue from external customers	$ 269	$ 35	$ 376	$ 65
Income from operations	189	1	255	8
Consolidated:				
Revenue from external customers	$ 269	$ 35	$ 376	$ 65
Loss from operations	(10,336)	(13,595)	(21,068)	(26,931)

A reconciliation of the total of the reportable segments' loss from operations to consolidated net loss before income taxes for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Segment loss from operations	$ (10,336)	$ (13,595)	$ (21,068)	$ (26,931)
Total other income (expense), net	(14,807)	9,061	(15,845)	9,043
Net loss before income taxes	$ (25,143)	$ (4,534)	$ (36,913)	$ (17,888)

Segment assets exclude corporate assets, such as cash, restricted cash, and corporate facilities. Total assets by reportable segment as of June 30, 2023 and December 31, 2022, were as follows:

(in thousands)	**June 30, 2023**	**December 31, 2022**
Total assets:		
Drugs	$ 17,994	$ 20,476
Supplements	326	386
Corporate	49,525	23,631
Consolidated	$ 67,845	$ 44,493

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 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 began in 2013 by innovating 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 human 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"), a 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.

Recent Developments of Our Clinical Programs

Amyotrophic Lateral Sclerosis

On June 15, 2023, we reported new data demonstrating a statistically significant reduction of plasma neurofilament light chain ("NfL") levels for CNM-Au8 treated participants compared to placebo after 24 weeks of treatment in the double-blind, placebo-controlled period of the Phase 2/3 HEALEY ALS Platform Trial, which evaluated the safety and efficacy of CNM-Au8 in patients with ALS. NfL is a key biomarker of neurodegeneration. NfL is released from neurons following axonal injury, especially in people living with ALS, where higher levels of NfL have been found to predict more rapid decline in clinical function and increased mortality risk. Surrogate biomarkers such as NfL have recently been used to support an approval by the U.S. Food and Drug Administration ("FDA") for the treatment of ALS.

The results are based on an analysis of the NfL biomarker across all Regimen C participants (CNM-Au8 or placebo, n=161), representing a broad ALS population, as the least-square mean ("LS Mean") change of the natural logarithm ("Ln") of the plasma NfL values with the standard error ("SE"):

- CNM-Au8 treatment reduced plasma NfL levels compared to placebo; LS Means on a Ln Scale for the 24-week difference of plasma NfL: CNM-Au8 = -0.024 (SE: 0.024); placebo = +0.076 (SE: 0.042); CNM-Au8 vs. placebo difference of LS Means on a Ln Scale = -0.100 (SE: 0.048), p=0.040.

In addition to the full analysis across all Regimen C participants, sensitivity analyses showed consistent significant reduction in plasma NfL levels versus placebo observed in specific populations generally considered at the greatest risk of ALS disease progression, including:

- **Faster progressors** (baseline pre-treatment ALSFRS-R slope ≥0.45 points/month (*post hoc*, n=107); Difference of LS Means on a Ln Scale (SE) = -0.144 (0.058); p=0.014.
- **Definite or probable ALS diagnosis** per El Escorial criteria (*post hoc*, n=125); Difference of LS Means on a Ln Scale (SE) = -0.124 (0.054); p=0.023.
- **Higher mortality risk** (baseline plasma NfL ≥ median, *post hoc*, n=79); Difference of LS Means on a Ln Scale (SE) = -0.150 (0.068); p=0.031.

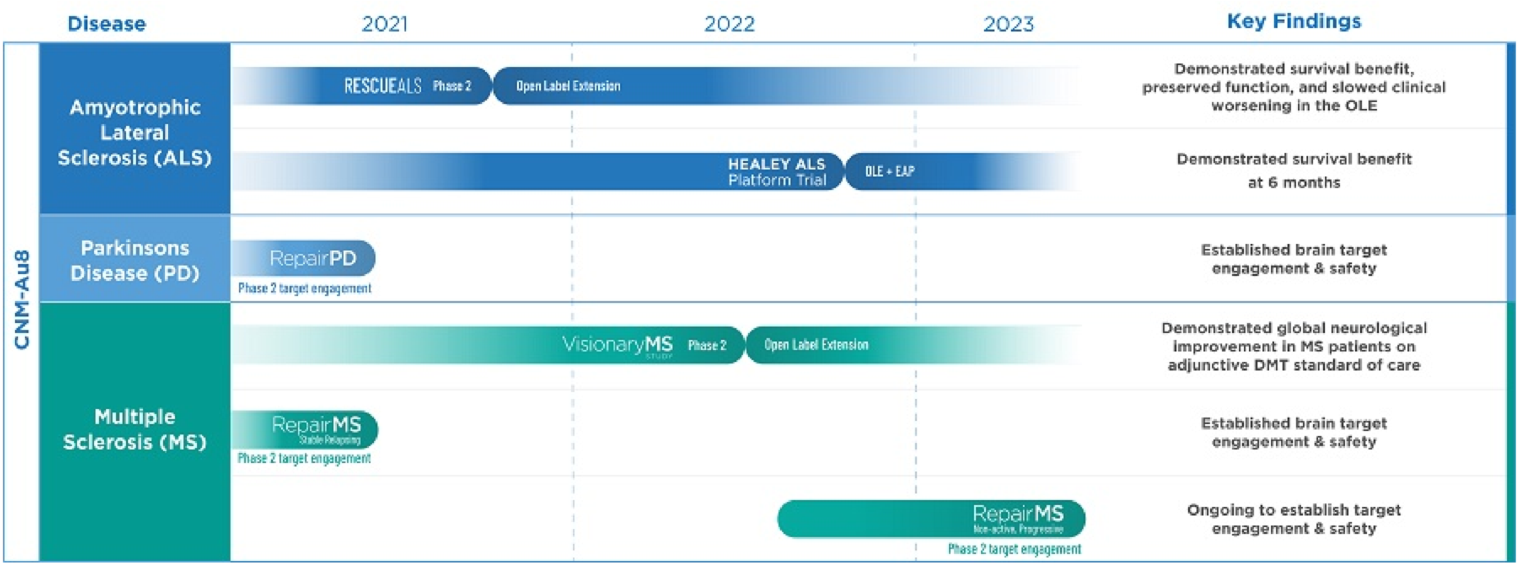
Analyses of NfL from serum samples specified as the primary blood matrix for analysis are underway. Additional biomarker and long-term survival data from the HEALEY ALS Platform Trial double-blind and open label extension ("OLE") periods have been collected and are undergoing testing preparatory for analysis, and we expect to report the data as follows: (i) plasma NfL data from the OLE in the third quarter of 2023, (ii) initial long-term survival data from the OLE in the third quarter of 2023, (iii) exploratory results for time to clinical worsening events and ALSFRS-R for the OLE in the fourth quarter of 2023, and (iv) data from additional biomarkers in late 2023. We also anticipate releasing updated clinical and survival data during the second half of 2023 from the OLE of our Phase 2 RESCUE-ALS clinical trial, which evaluated the efficacy, safety, and pharmacokinetics of CNM-Au8 in patients with early symptomatic ALS.

CNM-Au8 was well-tolerated without long term safety concerns in both RESCUE-ALS and the HEALEY ALS Platform Trial. We are presently discussing the design of an international Phase 3 study, RESTORE-ALS, with expert ALS clinical advisors and expect to initiate the trial in the first half of 2024. We plan to work closely with regulatory health authorities from the FDA and European Medicines Agency, ALS experts, and patient representatives to determine the proper path to support potential approval. We do not know when or if we will be able to file a New Drug Application ("NDA") with the FDA based on our accumulation of clinical evidence until we meet with the FDA in a Type B Meeting to discuss the totality of our long-term survival data and NfL data. We anticipate a Type B Meeting with the FDA in the fourth quarter of 2023. Based on the outcome of the Type B Meeting, we believe we could file an NDA with the FDA in the first half of 2024 with a potential accelerated approval Prescription Drug User Fee Act ("PDUFA") action date by the end of 2024.

Multiple Sclerosis

In February and March 2023, we reported updated exploratory data from our Phase 2 VISIONARY-MS clinical trial, which evaluated the efficacy and safety of CNM-Au8 in stable relapsing remitting MS patients. We expect additional results up to 144 weeks from the OLE in the fourth quarter of 2023. We also completed the first dosing cohort of REPAIR-MS, an open-label, investigator blinded Phase 2 clinical trial, and have initiated a second dosing cohort in non-active progressive MS patients which is expected to be complete in the first half of 2024. 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 our assets 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 2024. We are presently discussing the design of an international Phase 3 MS study with expert MS clinical advisors and expect to initiate the trial in the second half of 2024, contingent on funding.

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 May 2022, the FDA approved an orally administered version of edaravone, which has been available since 2017 as an intravenous infusion for the treatment of ALS. In September 2022, the FDA approved AMX0035, branded as Relyvrio, a drug from Amylyx Pharmaceuticals, Inc. for the treatment of ALS. AMX0035 previously received a conditional approval by Health Canada in June 2022.

On June 6, 2023, BrainStorm Cell Therapeutics Inc. (“BrainStorm”) announced the FDA will hold a meeting of the FDA Cellular, Tissue and Gene Therapies Advisory Committee on September 27, 2023, to review the Biologics License Application (“BLA”) for its investigational therapeutic NurOwn for the treatment of ALS, with a PDUFA action date by December 8, 2023.

On April 25, 2023, the FDA granted accelerated approval of tofersen, branded as QALSODY, a drug from Biogen Inc. for the treatment of SOD1-ALS. While tofersen did not meet the primary endpoint in the Phase 3 VALOR trial, trends favoring tofersen were seen across multiple secondary and exploratory measures of biologic activity and clinical function and 12-month integrated data from the Phase 3 VALOR trial and its OLE showed that earlier initiation of tofersen compared to delayed initiation slowed declines in clinical function, respiratory function, muscle strength, and quality of life in people with SOD1-ALS. Biogen Inc. sought accelerated approval of tofersen based on the use of plasma NfL as a surrogate biomarker that is reasonably likely to predict clinical benefit. Tofersen study results suggest reductions in plasma NfL preceded and predicted slowing of decline in measures of clinical and respiratory function, strength, and quality of life. Previously in March 2023, the Peripheral and Central Nervous System Drugs Advisory Committee voted 9 (yes) and 0 (no) as to whether a reduction in plasma NfL concentration in tofersen-treated patients is reasonably likely to predict clinical benefit of tofersen for treatment of patients with SOD1-ALS, and 3 (yes), 5 (no), and 1 (abstain) as to whether the clinical data from the placebo-controlled study and available long-term extension study results, with additional supporting results from the effects on relevant biomarkers (i.e. changes in plasma NfL concentration and/or reductions in SOD1), provide substantial evidence of the effectiveness of tofersen in the treatment of patients with SOD1-ALS. Additionally, in December 2022, the European Medicines Agency accepted the Marketing Authorization Application for review of tofersen.

Impact of the COVID-19 Pandemic

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic, including the resurgence of cases relating to the spread of new variants, on our business and operations is highly uncertain and difficult to predict, as the responses that we, other businesses, and governments are taking continue to evolve. Government measures taken in response to the COVID-19 pandemic have had a significant impact, both direct and indirect, on businesses, commerce, and economies worldwide, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The COVID-19 pandemic may affect our ability to initiate and complete preclinical studies and clinical trials, delay the initiation of future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In particular, we and our third-party contract research organizations (“CROs”) have faced disruptions that affected our ability to initiate and complete preclinical studies, caused manufacturing disruptions, and created delays at clinical trial site initiation and clinical trial enrollment, which ultimately led to the early conclusion of a clinical trial.

We are monitoring the potential impact of the COVID-19 pandemic on our business, financial condition, results of operations, and cash flows. While the COVID-19 pandemic has led to various research restrictions and led to pauses and early conclusion of one of our clinical trials, these impacts have been temporary and to date we have not experienced material business disruptions or incurred impairment losses in the carrying values of our assets as a result of the COVID-19 pandemic. We are not aware of any specific related event or circumstance that would require us to revise the estimates reflected in our condensed consolidated financial statements. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, financial condition, results of operations, and cash flows, including planned future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

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 and expanding.

Historically, substantially all of our research and development expenses relate to CNM-Au8, our lead asset, with the remainder spend on our CNM-ZnAg asset. Our research and development expenses are affected by the timing and advancement of our existing product pipeline as well as the timing and quantity of commencing 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, CRO activity, and manufacturing. We anticipate that our research and development expenses will decrease in 2023 due to the completion of many of our ongoing clinical trials but will increase in future years as we advance our assets into Phase 3 and explore potential accelerated approval with the FDA.

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 is contingent on the outcome of our Type B Meeting with the FDA, which is expected in the fourth quarter of 2023.

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 out 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 accumulation of clinical evidence, 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, including a reduction in executive 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) interest income and expense resulting from changes in fair value of our notes payable, (iii) changes in the fair value of our (a) common stock warrant liabilities and (b) Contingent Earn-outs, (iv) gains and losses on termination of leases, (v) commitment share expense from shares of Common Stock issued as a commitment fee, (vi) issuance costs allocated to liability-classified warrants, (vii) research and development tax credits, unconditional grants, and conditional grants for which applicable conditions have been met, and (viii) 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, 2023 and 2022 were as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Product revenue	$ 226	$ 2	11,200%	$ 290	$ 9	3,122%
Royalty revenue	43	33	30%	86	56	54%
Total revenue	269	35	669%	376	65	478%
Operating expenses:						
Cost of revenue	66	—	*	71	—	*
Research and development	6,615	9,166	(28)%	14,010	17,746	(21)%
General and administrative	3,924	4,464	(12)%	7,363	9,250	(20)%
Total operating expenses	10,605	13,630	(22)%	21,444	26,996	(21)%
Loss from operations	(10,336)	(13,595)	(24)%	(21,068)	(26,931)	(22)%
Total other income (expense), net	(14,807)	9,061	*	(15,845)	9,043	*
Net loss	$ (25,143)	$ (4,534)	455%	$ (36,913)	$ (17,888)	106%

Revenue

Product revenue relates to our Supplements segment 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 Supplements segment 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, 2023 and 2022, 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 for the three and six months ended June 30, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Change	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Change
CNM-Au8	$ 1,832	$ 3,028	(39)%	$ 3,965	$ 5,833	(32)%
CNM-ZnAg	116	484	(76)%	929	1,893	(51)%
Unallocated	1,221	2,179	(44)%	2,380	3,183	(25)%
Personnel	2,322	2,642	(12)%	4,639	5,260	(12)%
Stock-based compensation	1,124	833	35%	2,097	1,577	33%
Total research and development	$ 6,615	$ 9,166	(28)%	$ 14,010	$ 17,746	(21)%

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

(i) a decrease in expenses related to our lead drug candidate, CNM-Au8, primarily due to a decrease in expenses in the HEALEY ALS Platform Trial and our RESCUE-ALS, REPAIR-MS, REPAIR-PD, and VISIONARY-MS clinical trials due to completion of the blinded period of each trial, and a decrease in pre-clinical and non-clinical expenses; partially offset by an increase in expenses related to our two EAPs with the Sean M. Healey & AMG Center for ALS and the HEALEY ALS Platform Trial due to increased enrollment and expansion of one EAP;

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

(iii) a decrease in unallocated expenses, primarily due to decreased research, manufacturing, and materials expenses; partially offset by increased rent and utility expenses due to our newly-leased facility in Elkton, Maryland and our expanded facility in North East, Maryland, and increased depreciation expense.

(iv) a decrease in personnel expenses, primarily due to a reduction in headcount during the fourth quarter of 2022; and

(v) an increase in stock-based compensation expense, primarily due to the timing of award grants, vesting, and forfeitures for research and development personnel, partially offset by our decreased headcount in 2023.

General and Administrative Expense

General and administrative expense for the three and six months ended June 30, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Change	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Change
Directors' and officers' insurance	$ 399	$ 849	(53)%	$ 797	$ 1,698	(53)%
Legal	153	149	3%	261	327	(20)%
Finance and accounting	459	273	68%	718	684	5%
Public and investor relations	124	139	(11)%	268	469	(43)%
Personnel	1,184	1,260	(6)%	2,173	2,441	(11)%
Stock-based compensation	1,327	1,351	(2)%	2,577	2,809	(8)%
Other	278	443	(37)%	569	822	(31)%
Total general and administrative	$ 3,924	$ 4,464	(12)%	$ 7,363	$ 9,250	(20)%

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

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

(ii) a decrease in legal fees for the six months ended June 30, 2023, primarily due to a decrease in general corporate legal fees and intellectual property fees, partially offset by an increase in legal fees related to financing and fundraising;

(iii) an increase in finance and accounting fees, primarily due to increased fees from auditors, consultants, advisors, and other financial vendors; partially offset by decreased tax fees;

(iv) a decrease in fees related to our public and investor relations efforts;

(v) a decrease in personnel expenses, primarily due to a reduction in headcount during the fourth quarter of 2022;

(vi) a decrease in stock-based compensation expense, primarily due to the timing of award grants, vesting, and forfeitures for general and administrative personnel, and our decreased headcount in 2023; and

(vii) a decrease in other expenses, primarily due to a decrease in expenses related to supplies and equipment, facilities, corporate and liability insurance, information technology, travel, business development, and office and professional expenses; partially offset by increased depreciation expense.

Total Other Income (Expense), Net

Total other income (expense), net, for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Interest income	$ 213	$ 61	249%	$ 385	$ 85	353%
Interest expense	(1,104)	(751)	47%	(2,170)	(1,533)	42%
Gain on termination of lease	—	—	*	—	420	*
Commitment share expense	(3)	—	*	(402)	—	*
Issuance costs for common stock warrant liability	(333)	—	*	(333)	—	*
Loss on initial issuance of equity	(14,840)	—	*	(14,840)	—	*
Change in fair value of common stock warrant liabilities	(383)	20	*	(383)	2	*
Change in fair value of Clene Nanomedicine contingent earn-out liability	1,165	8,310	(86)%	1,110	8,253	(87)%
Change in fair value of Initial Stockholders contingent earn-out liability	150	1,066	(86)%	143	1,054	(86)%
Research and development tax credits and unrestricted grants	341	356	(4)%	655	655	0%
Other income (expense), net	(13)	(1)	1,200%	(10)	107	*
Total other income (expense), net	$ (14,807)	$ 9,061	*	$ (15,845)	$ 9,043	*

* 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 increased balances of cash and cash equivalents near the end of the period and increasing interest rates 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) a gain on termination of lease due to the termination of an operating lease for office space for the six months ended June 30, 2022;

(iii) 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;

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

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

(vi) a gain from a change in fair value of the Clene Nanomedicine Contingent Earn-out liability and Initial Stockholders Contingent Earn-out liability due to changes in the price of our Common Stock on Nasdaq and updates in the valuation model assumptions (see “Critical Accounting Estimates”);

(vii) a loss from a change in fair value of the common stock warrant liability related to the Original Avenue Warrant for the three and six months ended June 30, 2022, and the New Avenue Warrant and Tranche A Warrant for the three and six months ended June 30, 2023, due to the change in price of our Common Stock on Nasdaq and updates in the valuation model assumptions (see “Critical Accounting Estimates”). As of March 31, 2022, the Original Avenue Warrant liability qualified for equity classification and we remeasured the liability to fair value, recognized the change in fair value in the condensed consolidated statements of operations and comprehensive loss, and the liability was reclassified to additional paid-in capital;

(viii) a decrease in research and development tax credits and unrestricted grants due to changes in the amount of qualifying research and development expenses incurred and changes in the reimbursement percentage; and

(ix) an increase in other income (expense), net, primarily due to realized gains and losses on foreign currency transactions and other miscellaneous income and expense items.

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% for the six months ended June 30, 2023 and 2022. We are also subject to state income tax in Utah at a rate of 4.85% and 4.95%, respectively, for the six months ended June 30, 2023 and 2022, and in Maryland at a rate of 8.25% for the six months ended June 30, 2023 and 2022. As of June 30, 2023 and December 31, 2022, 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% and 25.00% for the six months ended June 30, 2023 and 2022, respectively. Clene Australia had no taxable income or provision for income taxes for the six months ended June 30, 2023 and 2022. We recorded other income of $0.7 million and $0.7 million for the six months ended June 30, 2023 and 2022, respectively, for research and development tax credits pertaining to Clene Australia for the 2023 and 2022 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 15.00% up to €395,000 of taxable income and 25.80% for taxable income in excess of €395,000 for the six months ended June 30, 2023, and 15.00% up to €245,000 of taxable income and 25.80% for taxable income in excess of €245,000 for the six months ended June 30, 2022. Clene Netherlands had no taxable income or provision for income taxes for the six months ended June 30, 2023 and 2022.

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 of our resources to the development of our drug candidates. We have financed our operations principally through the following sources:

- gross proceeds of $175.1 million from equity financing, including sales of common stock, preferred stock, warrants to purchase common stock, our ATM offering program, and our equity purchase agreement program;
- 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 $6.4 million from refundable research and development tax credits;
- gross proceeds of $2.9 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 $21.1 million and $26.9 million for the six months ended June 30, 2023 and 2022, respectively. Our accumulated deficit was $230.1 million and $193.2 million as of June 30, 2023 and December 31, 2022, respectively. Our cash, cash equivalents, and marketable securities totaled $49.2 million and $23.3 million as of June 30, 2023 and December 31, 2022, respectively, and net cash used in operating activities was $16.2 million and $22.8 million for the six months ended June 30, 2023 and 2022, 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. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the three months ended June 30, 2023, we raised approximately $37.4 million of net proceeds in an underwritten public equity offering. We have implemented cost-saving initiatives, including delaying and reducing research and development programs and commercialization efforts, reduction in executive compensation, a hiring freeze, 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 $0.1 million and $1.1 million of payments under finance and operating lease obligations, respectively; payment of principal and interest on notes payable totaling $3.2 million; and commitments under various agreements for capital expenditures totaling $0.4 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 $14,000 and $6.9 million of payments under finance and operating lease obligations, respectively; and interest and principal repayment of notes payable of $29.7 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, 2023 and 2022 were as follows:

	Six Months Ended June 30,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (16,239)	$ (22,814)
Net cash provided by (used in) investing activities	4,761	(20,857)
Net cash provided by financing activities	42,418	783
Effect of foreign exchange rate changes on cash	(29)	(147)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 30,911	$ (43,035)

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 $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 related to laboratory and office equipment and leasehold improvements; (ii) non-cash lease expense of $0.2 million; (iii) commitment share expense of $0.4 million related to the shares of Common Stock issued to Lincoln Park as an initial fee for Lincoln Park's commitment to purchase shares of Common Stock under a purchase agreement with the Company; (iv) issuance costs of $0.3 million from a public equity offering allocated to liability-classified warrants; (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) the changes in fair value of the Clene Nanomedicine and Initial Stockholders Contingent Earn-outs of $1.1 million and $0.1 million, respectively, primarily driven by the decrease of the closing price of our Common Stock on Nasdaq and changes in valuation model inputs; and (x) the change in fair value of the common stock warrant liabilities of $0.4 million, primarily driven by the increase of the closing price of our Common Stock on Nasdaq between the issuance date and period-end date and changes in valuation model inputs. The net change in operating assets and liabilities was primarily attributable to the following: (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.

Net cash used in operating activities was $22.8 million for the six months ended June 30, 2022, which resulted from a net loss of $17.9 million, adjusted for non-cash items totaling $4.2 million and a net change in operating assets and liabilities of $0.8 million. Significant non-cash items included (i) depreciation expense of $0.5 million related to laboratory and office equipment and leasehold improvements; (ii) non-cash lease expense of $0.2 million; (iii) stock-based compensation expense of $4.4 million; (iv) gain on termination of lease of $0.4 million; (v) accretion of debt discount of $0.4 million; (vi) non-cash interest expense of $0.1 million; and (vii) the changes in the fair value of the Clene Nanomedicine and Initial Stockholders Contingent Earn-outs of $8.3 million and $1.1 million, respectively. The changes in fair value of these instruments were primarily driven by the decrease of the closing price of our Common Stock on Nasdaq. The net change in operating assets and liabilities was primarily attributable to the following: (a) a decrease in accounts receivable of $49,000 and an increase in accounts payable of $1.5 million due to the timing of vendor invoicing and payments; (b) an increase in inventory of $0.1 million; (c) an increase in prepaid expenses and other current assets of $1.0 million due to the timing of vendor invoicing and payments, the timing of receipt of metals to be used in research and development, and an increase in Australia research and development credit receivable; (d) a decrease in accrued liabilities of $1.0 million primarily due to decreased accrued compensation and benefits; and (e) a decrease in operating lease obligations of $0.2 million.

Investing Activities

Net cash provided by investing activities was $4.8 million for the six months ended June 30, 2023, which consisted of proceeds from maturities of marketable securities of $5.0 million, partially offset by purchases of property and equipment of $0.2 million. Net cash used in investing activities was $20.9 million for the six months ended June 30, 2022, which consisted of (i) purchases of marketable securities of $24.6 million and (ii) purchases of property and equipment of $1.8 million, offset primarily by (iii) proceeds from maturity of marketable securities of $2.5 million and (iv) proceeds from sale of marketable securities of $3.0 million.

Financing Activities

Net cash provided by financing activities was $42.4 million for the six months ended June 30, 2023, which consisted of (i) proceeds from issuance of common stock and warrants, net of offering costs, of $42.1 million, and (ii) proceeds from the issuance of notes payable of $0.4 million; partially offset by (iii) payments of finance lease obligations of $46,000. Net cash provided by financing activities was $0.8 million for the six months ended June 30, 2022, which consisted of (i) proceeds from exercise of stock options of $0.3 million and (ii) proceeds from the issuance of notes payable of $0.7 million; offset primarily by (iii) payments of finance lease obligations of $0.1 million, (iv) payment of debt issuance costs of $30,000, and (v) payment of deferred offering costs of $0.1 million.

Public Offering

In June 2023, we sold 50,000,000 units at a sale price of $0.80 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 $1.10 per share (the "Tranche A Warrants"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $1.50 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 Warrants and Tranche B Warrants. We cannot predict when or if the Tranche A Warrants 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 2,895,090 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. The issuance and sale of Common Stock by us 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, and our prospectus supplement relating to the offering. On June 16, 2023, we delivered written notice to Canaccord that we were suspending and terminating the prospectus supplement (the “ATM Prospectus Supplement”) related to our Common Stock issuable pursuant to the ATM Agreement. We will not make any further sales of our securities pursuant to the ATM Agreement, unless and until a new prospectus supplement is filed. Other than the termination and suspension of the ATM Prospectus Supplement, the ATM Agreement remains in full force and effect.

Common Stock Purchase Agreement

During the three and six months ended June 30, 2023, we sold 400,000 shares of Common Stock under the purchase agreement (the “Purchase Agreement”) with Lincoln Park, issued 2,893 Additional Commitment Shares, and generated proceeds of $0.4 million. 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, and our prospectus supplement relating to the transaction. On June 16, 2023, we delivered written notice to Lincoln Park that we were terminating the prospectus supplement (the “Purchase Agreement Prospectus Supplement”) and the offering with respect to our 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.

Contingent Earn-Out Liabilities

In connection with the Reverse Recapitalization, certain stockholders are entitled to the Contingent Earn-outs payments based on achievement of certain milestones. In accordance with ASC 815, we classified the Contingent Earn-outs as liabilities and measured them at fair value on the date of the Reverse Recapitalization. We remeasure the liabilities at each reporting date and record the change in fair value as a component of other income (expense), net, in the condensed consolidated statements of operations and comprehensive loss. We estimate the fair value using a Monte Carlo valuation model, which requires significant judgment. The unobservable inputs include the expected stock price volatility, the risk-free interest rate, and the expected term. As of June 30, 2023 and December 31, 2022, the unobservable inputs were as follows:

	June 30, 2023	December 31, 2022
Expected stock price volatility	110.00%	115.00%
Risk-free interest rate	4.70%	4.20%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	2.5	3.00

The change in fair value of the Clene Nanomedicine Contingent Earn-out resulted in a gain of $1.1 million and $8.3 million for the six months ended June 30, 2023 and 2022, respectively. The change in fair value of the Initial Stockholders Contingent Earn-out resulted in a gain of $0.1 million and $1.1 million for the six months ended June 30, 2023 and 2022, respectively.

Convertible Notes

Pursuant to the 2021 Avenue Loan, $5.0 million of the outstanding principal is subject to the Avenue Conversion Feature. 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 this portion as convertible notes payable in the condensed consolidated balance sheets and did not separate the Avenue Conversion Feature 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, 2023 and December 31, 2022, the convertible note was carried at $4.7 million and $4.8 million, respectively.

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, 2023 and December 31, 2022, the convertible note was carried at $5.1 million and $5.0 million, respectively.

Common Stock Warrant Liabilities

Pursuant to an amendment to the 2021 Avenue Loan in June 2023, we issued a warrant to purchase 3,000,000 shares of Common Stock at $0.80 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 will 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. We estimate the fair value using a Black-Scholes option-pricing model with a probability weight for our estimate of the likelihood of settlement of the instrument upon a change of control transaction and our estimate of the likelihood of dissolution of the Company, which requires significant judgment. As of June 30, 2023, the unobservable inputs were as follows:

	June 30, 2023
Expected stock price volatility	90.00% – 110.00%
Risk-free interest rate	4.13% – 5.40%
Expected dividend yield	0.00%
Expected term (in years)	0.75 – 5.00
Probability of change of control	5.00%
Probability of dissolution	60.00%
Probability of other outcome	35.00%

Pursuant to an underwritten public offering in June 2023, we issued the Tranche A Warrants to purchase 50,000,000 shares of Common Stock at $1.10 per share and the Tranche B Warrants to purchase 50,000,000 shares of Common Stock at $1.50 per share. In accordance with ASC 815, we recognized the Tranche A Warrant as a derivative liability measured at fair value and will remeasure the Tranche A 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. 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, 2023, the unobservable inputs were as follows:

	June 30, 2023
Expected stock price volatility	100.00% – 110.00%
Risk-free interest rate	4.49% – 5.40%
Expected dividend yield	0.00%
Expected term (in years)	1.08 – 2.96
Probability of NDA acceptance	30.00%
Probability of fundamental transaction	5.00%
Probability of dissolution	60.00%
Probability of other outcome	5.00%

The Tranche B Warrant qualified for equity classification at issuance. We estimated the nonrecurring fair value measurement using a Black-Scholes option-pricing model with probability weights for the occurrence of the following events: (i) FDA approval 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. The unobservable inputs to the Black-Scholes option pricing model were as follows:

	June 30, 2023
Expected stock price volatility	100.00% – 110.00%
Risk-free interest rate	3.88% – 4.97%
Expected dividend yield	0.00%
Expected term (in years)	1.46 – 7.00
Probability of NDA approval	22.50%
Probability of fundamental transaction	5.00%
Probability of dissolution	71.50%
Probability of other outcome	1.00%

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, 2023 and 2022, the unobservable inputs were as follows:

	Six Months Ended June 30,	
	2023	2022
Expected stock price volatility	96.22% – 103.24%	89.57% – 93.38%
Risk-free interest rate	3.26% – 4.17%	1.65% – 3.00%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 – 6.43	5.00 – 6.98

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, 2023 and 2022.

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, 2023, 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, 2023, 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, 2022 and 2021, 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 2022, we made the following enhancements to our control environment:

- we have strengthened the experience of our internal accounting team, to provide oversight, structure and reporting lines, and to provide additional review over our disclosures, including hiring a new Chief Financial Officer;
- we engaged external consultants to provide support and to assist us in our evaluation of more complex applications of GAAP, and to assist us with documenting and assessing our accounting policies and procedures; and
- we implemented a new Enterprise Resource Planning system to enhance the accuracy of our financial records, enable the enforcement of systematic segregation of duties, and improve our information technology general controls environment.

Our remediation activities are continuing during 2023. 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, 2023, 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 2022 Annual Report on Form 10-K which was filed with the SEC on March 13, 2023. Except for the additional risk factor disclosed in Part II, Item 1A, Risk Factors, of our Quarterly Report on Form 10-Q for the period ended March 31, 2023, which was filed with the SEC on May 12, 2023, there have been no material changes to the risk factors since previously disclosed in the 2022 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

None.

Table of Contents

Item 6. Exhibits

Exhibit Number	Exhibit Description
1.1	Underwriting Agreement, dated June 16, 2023, by and between Clene Inc. and Canaccord Genuity LLC (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed by the Registrant on June 16, 2023).
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	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).
4.1	Form of Tranche A Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Registrant on June 16, 2023).
4.2	Form of Tranche B Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed by the Registrant on June 16, 2023).
4.3	Form of Avenue Venture Opportunities Fund, L.P. Warrant to Purchase Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Registrant on June 30, 2023).
10.1#	Second Amendment to Supplement to Loan and Security Agreement, dated June 27, 2023, by and among Avenue Venture Opportunities Fund, L.P., Clene Inc., and Clene Nanomedicine, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on June 30, 2023).
10.2##	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 11, 2023).
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.
\# Schedules and similar attachments to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. We agree to furnish supplementally a copy of such omitted materials to the SEC upon request.
\#\# 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 14, 2023	By:	/s/ Robert Etherington
	Name:	Robert Etherington
	Title:	President, Chief Executive Officer and Director
Dated: August 14, 2023	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 14, 2023

/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 14, 2023

/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, 2023, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2023

/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, 2023, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2023

/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.