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 March 31, 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 May 9, 2023 was 78,393,865.

CLENE INC.
Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2023

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,442	$ 18,332
Marketable securities	—	4,983
Accounts receivable	63	189
Inventory	88	43
Prepaid expenses and other current assets	6,229	5,648
Total current assets	24,822	29,195
Restricted cash	58	58
Operating lease right-of-use assets	4,494	4,602
Property and equipment, net	10,514	10,638
TOTAL ASSETS	$ 39,888	$ 44,493
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 608	$ 3,014
Accrued liabilities	5,933	3,863
Operating lease obligations, current portion	508	488
Finance lease obligations, current portion	76	74
Notes payable, current portion	9,751	6,418
Total current liabilities	16,876	13,857
Operating lease obligations, net of current portion	5,399	5,557
Finance lease obligations, net of current portion	3	34
Notes payable, net of current portion	6,713	9,483
Convertible notes payable	9,907	9,770
Clene Nanomedicine contingent earn-out liability	2,319	2,264
Initial Stockholders contingent earn-out liability	298	291
TOTAL LIABILITIES	41,515	41,256
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 77,987,349 and 74,759,591 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	8	7
Additional paid-in capital	203,133	196,246
Accumulated deficit	(204,989)	(193,219)
Accumulated other comprehensive income	221	203
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(1,627)	3,237
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 39,888	$ 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 March 31,	
	2023	2022
Revenue:		
Product revenue	$ 64	$ 7
Royalty revenue	43	23
Total revenue	107	30
Operating expenses:		
Cost of revenue	5	—
Research and development	7,395	8,580
General and administrative	3,439	4,786
Total operating expenses	10,839	13,366
Loss from operations	(10,732)	(13,336)
Other income (expense), net:		
Interest income	172	24
Interest expense	(1,066)	(782)
Gain on termination of lease	—	420
Commitment share expense	(399)	—
Change in fair value of common stock warrant liability	—	(18)
Change in fair value of Clene Nanomedicine contingent earn-out liability	(55)	(57)
Change in fair value of Initial Stockholders contingent earn-out liability	(7)	(12)
Research and development tax credits and unrestricted grants	314	299
Other income (expense), net	3	108
Total other income (expense), net	(1,038)	(18)
Net loss before income taxes	(11,770)	(13,354)
Income tax expense	—	—
Net loss	(11,770)	(13,354)
Other comprehensive income:		
Unrealized gain (loss) on available-for-sale securities	14	(50)
Foreign currency translation adjustments	4	50
Total other comprehensive income	18	—
Comprehensive loss	$ (11,752)	$ (13,354)
Net loss per share – basic and diluted	$ (0.15)	$ (0.21)
Weighted average common shares used to compute basic and diluted net loss per share	76,049,665	62,852,863

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)
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

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (11,770)	$ (13,354)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	402	195
Non-cash lease expense	108	52
Commitment share expense	399	—
Change in fair value of common stock warrant liability	—	18
Change in fair value of Clene Nanomedicine contingent earn-out liability	55	57
Change in fair value of Initial Stockholders contingent earn-out liability	7	12
Stock-based compensation expense	2,223	2,202
Gain on termination of lease	—	(420)
Accretion of debt discount	250	227
Non-cash interest expense	82	45
Changes in operating assets and liabilities:		
Accounts receivable	126	49
Inventory	(45)	3
Prepaid expenses and other current assets	(581)	(1,691)
Accounts payable	(2,406)	1,389
Accrued liabilities	2,070	(2,069)
Operating lease obligations	(138)	201
Net cash used in operating activities	(9,218)	(13,084)
Cash flows from investing activities:		
Purchases of marketable securities	—	(23,586)
Proceeds from maturities of marketable securities	5,000	—
Purchases of property and equipment	(278)	(936)
Net cash provided by (used in) investing activities	4,722	(24,522)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	267
Proceeds from issuance of common stock, net of offering costs	4,266	—
Payments of finance lease obligations	(28)	(32)
Proceeds from the issuance of notes payable	350	—
Net cash provided by financing activities	4,588	235
Effect of foreign exchange rate changes on cash and restricted cash	18	13
Net increase (decrease) in cash, cash equivalents and restricted cash	110	(37,358)
Cash, cash equivalents and restricted cash – beginning of period	18,390	50,346
Cash, cash equivalents and restricted cash – end of period	$ 18,500	$ 12,988
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	18,442	12,930
Restricted cash	58	58
Cash, cash equivalents and restricted cash	$ 18,500	$ 12,988
Supplemental disclosure of non-cash investing and financing activities:		
Lease liability arising from obtaining right-of-use assets, leasehold improvements, and lease incentives	$ —	$ 2,343
Lease liability settled through termination of lease	$ —	$ 602
Reclassification of common stock warrant liability to permanent equity	$ —	$ 305
Supplemental cash flow information:		
Cash paid for interest expense	$ 982	$ 493

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 $10.7 million and $13.3 million for the three months ended March 31, 2023 and 2022, respectively. Our accumulated deficit was $205.0 million and $193.2 million as of March 31, 2023 and December 31, 2022, respectively. Our cash, cash equivalents, and marketable securities totaled $18.4 million and $23.3 million as of March 31, 2023 and December 31, 2022, respectively, and net cash used in operating activities was $9.2 million and $13.1 million for the three months ended March 31, 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. 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. Subsequent to March 31, 2023, we have raised $0.4 million through our equity purchase agreement. 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 months ended March 31, 2023 and 2022 are unaudited.

Results of operations for the three months ended March 31, 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 months ended March 31, 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 $0.1 million in raw materials and $19,000 in finished goods as of March 31, 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 did not fulfill any grant conditions or performance obligations during the three months ended March 31, 2023 and 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 (deficit) 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 (deficit). We also incur foreign exchange transaction gains and losses for purchases denominated in foreign currencies. Foreign exchange transaction gains and losses are included in other income (expense), net, as incurred.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The only elements of other comprehensive loss in any periods presented were 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.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The amendments in this update, among other things, require the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Financial institutions and other organizations will now use forward-looking information to better inform their credit loss estimates. As a smaller reporting company, the guidance was effective for our fiscal years beginning after December 15, 2022. The adoption of this guidance did not have an impact on our condensed consolidated financial statements.

Note 3. Marketable Securities

Available-for-Sale Securities

We had no available-for-sale securities as of March 31, 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

We received proceeds from maturities of available-for-sale securities of $5.0 million and $0 for the three months ended March 31, 2023 and 2022, respectively. 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 March 31, 2023 and December 31, 2022 were as follows:

(in thousands)	March 31, 2023	December 31, 2022
Research and development tax credits receivable	$ 3,051	$ 2,777
Metals to be used in research and development	2,216	2,290
Other	962	581
Total prepaid expenses and other current assets	$ 6,229	$ 5,648

Note 5. Property and Equipment, Net

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

(in thousands)	March 31, 2023	December 31, 2022
Lab equipment	$ 3,923	$ 3,934
Office equipment	178	177
Computer software	459	459
Leasehold improvements	9,966	5,677
Construction in progress	1,652	5,664
	16,178	15,911
Less accumulated depreciation	(5,664)	(5,273)
Total property and equipment, net	$ 10,514	$ 10,638

Depreciation expense recorded in research and development expense and general and administrative expense for the three months ended March 31, 2023 and 2022 was as follows:

	Three Months Ended March 31,	
(in thousands)	2023	2022
General and administrative	$ 67	$ 29
Research and development	335	166
Total depreciation expense	$ 402	$ 195

Note 6. Accrued Liabilities

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

(in thousands)	March 31, 2023	December 31, 2022
Accrued compensation and benefits	$ 2,638	$ 2,007
Accrued CRO and clinical fees	2,752	1,297
Other	543	559
Total accrued liabilities	$ 5,933	$ 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 March 31, 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 7.1 years and 7.3 years, respectively.

Finance Leases

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

(in thousands)	March 31, 2023	December 31, 2022
Lab equipment	$ 408	$ 408
Work in process	228	228
Total	636	636
Less accumulated depreciation	(346)	(326)
Net	$ 290	$ 310

As of March 31, 2023 and December 31, 2022, our finance lease obligations had a weighted-average interest rate of 10.8% and 10.2%, respectively; and a weighted-average remaining term of 1.0 years and 1.2 years, respectively.

Maturity Analysis of Leases

The maturity analysis of our finance and operating leases as of March 31, 2023 was as follows:

(in thousands)	Finance Leases	Operating Leases
2023 (remainder)	$ 65	$ 767
2024	27	1,171
2025	—	1,202
2026	—	1,231
2027	—	1,129
2028	—	1,092
Thereafter	—	1,694
Total undiscounted cash flows	92	8,286
Less amount representing interest/discounting	(13)	(2,379)
Present value of future lease payments	79	5,907
Less lease obligations, current portion	(76)	(508)
Lease obligations, long term portion	$ 3	$ 5,399

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 months ended March 31, 2023 and 2022 were as follows:

(in thousands)	Three Months Ended March 31, 2023	2022
Finance lease costs:		
Amortization	$ 20	$ 20
Interest on lease liabilities	6	5
Operating lease costs	253	230
Variable lease costs	50	65
Total lease costs	$ 329	$ 320

Supplemental Cash Flow Information

(in thousands)	Three Months Ended March 31, 2023	2022
Operating cash flows from operating leases	$ (303)	$ (295)
Operating cash flows from finance leases	$ (6)	$ (5)
Financing cash flows from finance leases	$ (28)	$ (32)

Note 8. Notes Payable and Convertible Notes Payable

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

(in thousands, except interest rates)	Stated Interest Rate	March 31, 2023	December 31, 2022
Notes payable			
Advance Cecil, Inc. (commenced April 2019)	8.00%	$ 132	$ 130
Maryland DHCD (commenced February 2019)	8.00%	664	654
Maryland DHCD (commenced May 2022)	6.00%	1,032	682
Avenue Venture Opportunities Fund, L.P. (commenced May 2021)	14.60%	15,000	15,000
		16,828	16,466
Accrued and unpaid interest		35	22
Less unamortized discount and debt issuance costs		(399)	(587)
Less notes payable, current portion, net of unamortized discount and debt issuance costs		(9,751)	(6,418)
Total notes payable, net of current portion		$ 6,713	$ 9,483
Convertible notes payable			
Avenue Venture Opportunities Fund, L.P. (commenced May 2021)	14.60%	$ 5,000	$ 5,000
Maryland DHCD (commenced December 2022)	6.00%	5,000	5,000
		10,000	10,000
Accrued and unpaid interest		83	7
Less unamortized discount and debt issuance costs		(176)	(237)
Total convertible notes payable		$ 9,907	$ 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 March 31, 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 March 31, 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 March 31, 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 $12,000 for the three months ended March 31, 2023.

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 months ended March 31, 2023, we recognized (i) total interest expense of $74,000, (ii) coupon interest expense of $75,000, and (iii) amortization of debt issuance costs of ($1,000), 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 March 31, 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 March 31, 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 March 31, 2023 and December 31, 2022, the interest rate was 14.60% 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 are interest-only for the first twelve months and were extended an additional twelve months due to our achievement of a statistically significant result in certain clinical trials, followed by equal monthly installments of principal plus interest payments at the variable rate then in effect until the end of the 42-month term on December 1, 2024. An additional payment of 4.25% of the funded principal, equal to $0.9 million (the "Final Payment"), is due at maturity and was recorded as a debt premium. We incurred $0.6 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 March 31, 2023 and December 31, 2022, unamortized debt discount and issuance costs related to the convertible note were $0.1 million and $0.2 million, respectively. For the convertible note for the three months ended March 31, 2023 and 2022, we recognized (i) total interest expense of $240,000 and $180,000, respectively; (ii) coupon interest expense of $177,000 and $123,000, respectively; and (iii) amortization of debt discount and issuance costs of $63,000 and $57,000, respectively; and the effective interest rate was 20.17% and 15.71%, 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 March 31, 2023 and 2022, respectively.

Additionally, we issued a warrant to purchase Common Stock to Avenue 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 "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 $1.5 million, which was recorded as a debt discount.

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)	$ —	$ —	$ 6,667	$ —	$ —
2024	—	—	13,333	—	—
2025	—	—	—	347	—
2026	—	—	—	369	—
2027	—	—	—	317	—
2028	—	—	—	—	5,000
Thereafter	664	132	—	—	—
Subtotal of future principal payments	664	132	20,000	1,033	5,000
Accrued and unpaid interest	—	—	—	35	83
Less unamortized discount and debt issuance costs	—	—	(497)	(26)	(52)
Total	$ 664	$ 132	$ 19,503	$ 1,042	$ 5,031

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 March 31, 2023 and December 31, 2022, we had commitments under various agreements for capital expenditures totaling $0.5 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, and (v) a collaboration with a third-party to develop CNM-Au8 for the treatment of MS. As of March 31, 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 $0.2 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.

Note 10. Income Taxes

The components of loss before income taxes for the three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31,	
(in thousands)	**2023**	**2022**
United States	$ (11,546)	$ (12,957)
Foreign	(224)	(397)
Net loss before income taxes	$ (11,770)	$ (13,354)

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 March 31, 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 March 31, 2023, 5,367,340 stock options remained outstanding under the 2014 Stock Plan.

The Clene Inc. 2020 Stock Plan (the "2020 Stock Plan") was adopted in December 2020 and 12,000,000 shares of Common Stock were reserved for issuance thereunder. As of March 31, 2023, a total of 11,933,488 stock options and other stock awards had been granted under the 2020 Stock Plan, and 66,512 shares remained available for future grant. On May 9, 2023, the 2020 Stock Plan was amended and the shares reserved for issuance thereunder was increased by 6,400,000 shares.

Stock-Based Compensation Expense

Stock-based compensation expense recorded in research and development expense and general and administrative expense for the three months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31, 2023	2022
General and administrative	$ 1,250	$ 1,458
Research and development	973	744
Total stock-based compensation expense	$ 2,223	$ 2,202

Stock-based compensation expense by award type for the three months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31, 2023	2022
Stock options	$ 2,222	$ 2,202
Stock awards	1	—
Total stock-based compensation expense	$ 2,223	$ 2,202

Stock Options

Outstanding stock options and related activity for the three months ended March 31, 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	1,077,432	1.30	9.89	—
Forfeited	(132,325)	5.83	—	—
Outstanding – March 31, 2023	16,205,404	$ 2.85	7.22	$ 2,923
Vested and exercisable – March 31, 2023	8,085,513	$ 2.76	5.29	$ 2,855
Vested, exercisable or expected to vest – March 31, 2023	16,205,404	$ 2.85	7.22	$ 2,923

As of March 31, 2023 and December 31, 2022, we had approximately $16.8 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 2.36 years and 2.58 years, respectively.

The weighted-average grant-date fair value of stock options granted during the three months ended March 31, 2023 and 2022 was $0.99 and $2.25, respectively. The assumptions used to calculate the fair value of stock options granted during the three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31, 2023	2022
Expected stock price volatility	96.22% – 103.24%	89.57% – 93.07%
Risk-free interest rate	3.38% – 3.98%	1.65% – 2.02%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 – 6.08	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 three months ended March 31, 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
Forfeited	(448)	9.84
Unvested balance – March 31, 2023	812,170	$ 9.38

As of March 31, 2023, we had approximately $0.1 million of unrecognized stock-based compensation costs related to non-vested stock awards which is expected to be recognized over a weighted-average period of 0.98 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 March 31, 2023 is as follows:

	March 31, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents				
Money market funds	$ 15,981	$ —	$ —	$ 15,981
Clene Nanomedicine contingent earn-out liability	—	—	2,319	2,319
Initial Stockholders contingent earn-out liability	—	—	298	298

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 three months ended March 31, 2023 were as follows:

(in thousands)	**Clene Nanomedicine Contingent Earn-out**	**Initial Stockholders Contingent Earn-out**
Balance – December 31, 2022	$ 2,264	$ 291
Change in fair value	55	7
Balance – March 31, 2023	$ 2,319	$ 298

Changes in the fair value of our Level 3 financial instruments for the three months ended March 31, 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	18	57	12
Reclassification from liability to equity	(305)	—	—
Balance – March 31, 2022	$ 187	$ 18,157	$ 2,329

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 Liability

The 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.

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:

	March 31, 2023	December 31, 2022
Expected stock price volatility	115.00%	115.00%
Risk-free interest rate	3.90%	4.20%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	2.75	3.00

Note 13. Capital Stock

As of March 31, 2023 and December 31, 2022, our amended and restated certificate of incorporation (the "Certificate") authorized us to issue 150,000,000 shares of Common Stock, par value $0.0001 per share, and 1,000,000 shares of preferred stock, par value $0.0001 per share. As of March 31, 2023 and December 31, 2022, we had 77,987,349 and 74,759,591 shares of Common Stock issued and outstanding, respectively, and no shares of preferred stock issued or outstanding. On May 9, 2023, our stockholders approved an amendment to the Certificate which increased the number of authorized shares of Common Stock to 300,000,000 shares.

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 March 31, 2023 and December 31, 2022, outstanding warrants to purchase shares of Common Stock were as follows:

Date Exercisable	Number of Shares Issuable		Exercise Price	Expiration
December 2020	2,407,500	(1)	$ 11.50	December 2025
December 2020	24,583	(2)	$ 11.50	December 2025
December 2020	1,929,111	(3)	$ 1.97	April 2023
May 2021	115,851	(4)	$ 8.63	May 2026
Total	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 March 31, 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 March 31, 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 March 31, 2023 and December 31, 2022, no warrants had been exercised. As of April 2023, the warrants expired.

(4) Consists of 115,851 shares of Common Stock underlying the Avenue Warrant. As of March 31, 2023 and December 31, 2022, the warrant had not 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.

Common Stock Sales Agreement

In April 2022, we entered into an Equity Distribution Agreement (the "ATM Agreement") with Canaccord Genuity LLC 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, if any, by us under the ATM Agreement will be 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.

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 months ended March 31, 2023, we sold 2,895,090 shares of Common Stock under the ATM Agreement, generated gross proceeds of $4.5 million, and paid commissions of $0.1 million.

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 is 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.

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.

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 March 31, 2023.

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. During the three months ended March 31, 2023, we did not make any sales under the Purchase Agreement.

Note 14. Net Loss Per Share

The computation of basic and diluted net loss per share attributable to common stockholders for the three months ended March 31, 2023 and 2022 was as follows:

(in thousands, except share and per share data)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Numerator:		
Net loss attributable to common stockholders	$ (11,770)	$ (13,354)
Denominator:		
Weighted average common shares outstanding	76,049,665	62,852,863
Net loss per share attributable to common stockholders – basic and diluted	$ (0.15)	$ (0.21)

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 months ended March 31, 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 March 31,	
	2023	2022
Convertible notes payable (see Note 8)	1,732,703	482,703
Common stock warrants (see Note 13)	4,477,045	4,477,045
Options to purchase common stock (see Note 11)	16,205,404	11,944,789
Unvested restricted stock awards (see Note 11)	812,170	914,876
Contingent earn-out shares (see Note 2)	6,592,334	6,592,334
Total	29,819,656	24,411,747

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 months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Product revenue from related parties	$ 63	$ —
Royalty revenue from related parties	43	23
Total revenue from related parties	$ 106	$ 23

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 months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Drugs:		
Revenue from external customers	$ —	$ —
Loss from operations	(10,798)	(13,343)
Supplements:		
Revenue from external customers	$ 107	$ 30
Income from operations	66	7
Consolidated:		
Revenue from external customers	$ 107	$ 30
Loss from operations	(10,732)	(13,336)

A reconciliation of the total of the reportable segments' loss from operations to consolidated net loss before income taxes for the three months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Segment loss from operations	$ (10,732)	$ (13,336)
Total other income (expense), net	(1,038)	(18)
Net loss before income taxes	$ (11,770)	$ (13,354)

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

(in thousands)	March 31, 2023	December 31, 2022
Total assets:		
Drugs	$ 20,875	$ 20,476
Supplements	272	386
Corporate	18,741	23,631
Consolidated	$ 39,888	$ 44,493

Note 17. Subsequent Events

Common Stock Purchase Agreement

Subsequent to March 31, 2023, we sold 400,000 shares of Common Stock under the Purchase Agreement with Lincoln Park and generated proceeds of $0.4 million, and we issued 2,893 Additional Commitment Shares pursuant to the Purchase Agreement. 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 offering.

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

In October 2022, we reported topline data from the Phase 2/3 HEALEY ALS Platform Trial, which evaluated the safety and efficacy of CNM-Au8 in patients with ALS. In March 2023, we reported additional exploratory results for time to clinical worsening events. The full analyses, including data on biomarkers of neurodegeneration and additional exploratory efficacy results, are expected to be received from the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital in mid-2023. The open label extension ("OLE") will continue to follow participants for an additional 52-week treatment period and we expect matured survival data in mid-2023. Additionally, we expect exploratory efficacy results from the OLE in the second half of 2023. Based on numerous requests from clinical trial sites, we have decided to increase the capacity of the second Expanded Access Program ("EAP") up to 200 participants, contingent on the magnitude of available funding, with expansion to sites across the U.S. The expansion protocol amendment was filed with the FDA in December 2022 and additional sites continue to be enrolled.

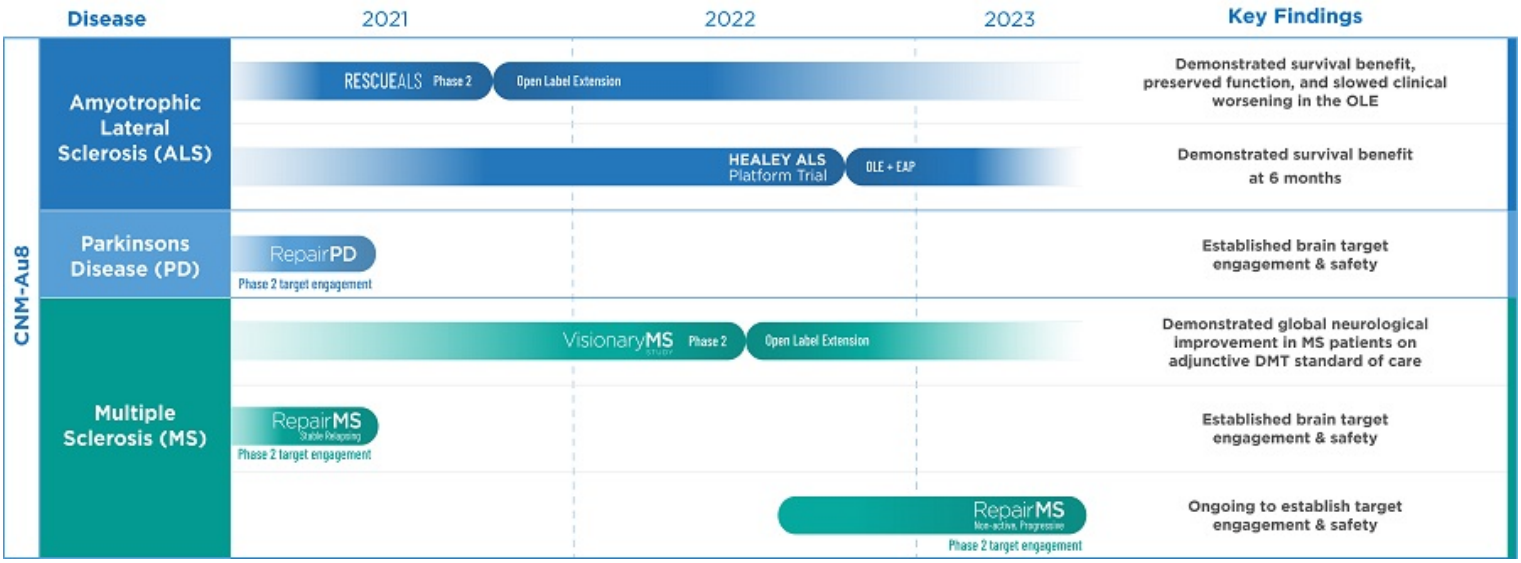
In March 2023, we reported data from the most recent 120-week data cut of the OLE of our Phase 2 RESCUE-ALS clinical trial, which evaluated the efficacy, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in patients with early symptomatic ALS, and we anticipate releasing updated clinical and survival data during 2023.

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, contingent on funding. We plan to work closely with regulatory health authorities from the U.S. Food and Drug Administration ("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 an end of Phase 2 meeting which is expected in the third quarter of 2023. If the forthcoming biomarker data is supportive, we anticipate a request-to-file NDA meeting with the FDA in the fourth quarter of 2023. Based on the outcome of the request-to-file meeting, we believe we could file an NDA with the FDA in mid-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 exploratory results up to 144 weeks from the OLE in the second half 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 second half of 2023. 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 fourth quarter of 2023. 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 mid-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.

In February 2023, Prilenia Therapeutics B.V. announced its pridopidine investigational drug did not meet the primary and key secondary endpoints in the HEALEY ALS Platform Trial, but consistent, positive trends were observed among participants receiving pridopidine across several pre-specified secondary and exploratory endpoints, including a reduction in neurofilament light chain ("NfL") levels in rapidly declining patients with disease duration less than 18 months compared to placebo.

On March 27, 2023, BrainStorm Cell Therapeutics Inc. ("BrainStorm") announced the FDA will hold a meeting of the FDA Peripheral and Central Nervous System Drugs Advisory Committee ("PCNSDAC") to review the Biologics License Application ("BLA") for its investigational therapeutic NurOwn for the treatment of ALS. BrainStorm completed a Phase 3 trial in ALS which did not meet the primary and secondary endpoints, however a pre-specified subgroup of participants showed a trend to a meaningful increase in the clinical response with NurOwn compared to placebo and met the secondary endpoint of average ALSFRS-R change from baseline to week 28. Additional post-hoc sensitivity analyses also showed a statistical trend towards a clinically meaningful treatment effect with NurOwn across subgroups. Finally, biomarker data in all trial participants also showed consistent patterns of NurOwn reducing markers of inflammation and neurodegeneration, and increasing neuroprotective and anti-inflammatory markers relative to placebo.

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. Neurofilaments are normal proteins found in healthy neurons, that are increased in blood and cerebrospinal fluid when damage has been done to neurons or their axons and are a marker of neurodegeneration. In ALS, higher levels of plasma NfL have been found to predict more rapid decline in clinical function and shortened survival. 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 PCNSDAC 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 end of Phase 2 meetings with the FDA, which are expected in the third quarter of 2023 after we receive the biomarker data and efficacy parameters that is forthcoming from the Healey ALS Platform Trial, and our discussions with regulatory health authorities, ALS experts, and patient representatives to determine the proper path to support potential approval of CNM-Au8.

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) changes in the fair value of our (a) common stock warrant liability and (b) Contingent Earn-outs, (ii) interest income and interest expense, (iii) interest income and expense resulting from changes in fair value of our notes payable, (iv) gains and losses on termination of leases, and (v) research and development tax credits, unconditional grants, and conditional grants for which applicable conditions have been met.

Results of Operations

Our results of operations for the three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31,		
(in thousands)	**2023**	**2022**	**Change**
Product revenue	$ 64	$ 7	814%
Royalty revenue	43	23	87%
Total revenue	107	30	257%
Operating expenses:			
Cost of revenue	5	—	*
Research and development	7,395	8,580	(14)%
General and administrative	3,439	4,786	(28)%
Total operating expenses	10,839	13,366	(19)%
Loss from operations	(10,732)	(13,336)	(20)%
Total other income (expense), net	(1,038)	(18)	5,667%
Net loss	$ (11,770)	$ (13,354)	(12)%

Revenue

Product revenue totaled $0.1 million and $7,000 for the three months ended March 31, 2023 and 2022, respectively, in our Supplements segment related to (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." During the three months ended March 31, 2023, changes in product revenue were due to the timing of purchases of Zinc Factor and Gold Factor by 4Life under the supply agreement.

Royalty revenue totaled $43,000 and $23,000 for the three months ended March 31, 2023 and 2022, respectively, under an exclusive and royalty-bearing license agreement with 4Life relating to the sale of Gold Factor.

Cost of Revenue

Cost of revenue totaled $5,000 and $0 for the three months ended March 31, 2023 and 2022, respectively, relating 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 months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31, 2023	2022	Change
CNM-Au8	$ 2,133	$ 2,805	(24)%
CNM-ZnAg	813	1,409	(42)%
Unallocated	1,159	1,004	15%
Personnel	2,317	2,618	(11)%
Stock-based compensation	973	744	31%
Total research and development	$ 7,395	$ 8,580	(14)%

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 the 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, an increase in expenses in the REPAIR-MS clinical trial due to the initiation of the second dosing cohort, and an increase in expenses in the RESCUE-ALS clinical trial due to the ongoing OLE;

(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) an increase in unallocated expenses, primarily due to 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; partially offset by decreased research, manufacturing, and materials expenses;

(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 months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31, 2023	2022	Change
Directors' and officers' insurance	$ 398	$ 849	(53)%
Legal	108	178	(39)%
Finance and accounting	259	411	(37)%
Public and investor relations	144	330	(56)%
Personnel	989	1,181	(16)%
Stock-based compensation	1,250	1,458	(14)%
Other	291	379	(23)%
Total general and administrative	$ 3,439	$ 4,786	(28)%

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 after completing registration statement filings with the SEC and decreased fees related to financing and fundraising, partially offset by an increase in other general corporate legal fees;

(iii) a decrease in finance and accounting fees, including decreased fees from consultants and other financial vendors; decreased fees for various financial institutions, investment bankers, advisors, and auditors; and 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, travel, business development, and office and professional expenses; partially offset by an increase in expenses related to depreciation and information technology.

Total Other Income (Expense), Net

Total other income (expense), net, for the three months ended March 31, 2023 and 2022 was as follows:

(in thousands)	Three Months Ended March 31, 2023	2022	Change
Interest income	$ 172	$ 24	617%
Interest expense	(1,066)	(782)	36%
Gain on termination of lease	—	420	*
Commitment share expense	(399)	—	*
Change in fair value of common stock warrant liability	—	(18)	*
Change in fair value of Clene Nanomedicine contingent earn-out liability	(55)	(57)	(4)%
Change in fair value of Initial Stockholders contingent earn-out liability	(7)	(12)	(42)%
Research and development tax credits and unrestricted grants	314	299	5%
Other income (expense), net	3	108	(97)%
Total other income (expense), net	$ (1,038)	$ (18)	5,667%

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

(i) an increase in interest income primarily due to increasing interest rates 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 three months ended March 31, 2022;

(iii) other expense for the three months ended March 31, 2023, 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) a loss 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”);

(v) a loss from a change in fair value of the common stock warrant liability related to the Avenue Warrant for the three months ended March 31, 2022, due to the change in price of our Common Stock on Nasdaq and updates in the valuation model assumptions. As of March 31, 2022, the 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;

(vi) an increase 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

(vii) a decrease 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 three months ended March 31, 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 three months ended March 31, 2023 and 2022, and in Maryland at a rate of 8.25% for the three months ended March 31, 2023 and 2022. As of March 31, 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 three months ended March 31, 2023 and 2022, respectively. Clene Australia had no taxable income or provision for income taxes for the three months ended March 31, 2023 and 2022. We recorded other income of $0.3 million and $0.3 million for the three months ended March 31, 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 three months ended March 31, 2023, and 15.00% up to €245,000 of taxable income and 25.80% for taxable income in excess of €245,000 for the three months ended March 31, 2022. Clene Netherlands had no taxable income or provision for income taxes for the three months ended March 31, 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 $135.1 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 $2.2 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 $10.7 million and $13.3 million for the three months ended March 31, 2023 and 2022, respectively. Our accumulated deficit was $205.0 million and $193.2 million as of March 31, 2023 and December 31, 2022, respectively. Our cash, cash equivalents, and marketable securities totaled $18.4 million and $23.3 million as of March 31, 2023 and December 31, 2022, respectively, and net cash used in operating activities was $9.2 million and $13.1 million for the three months ended March 31, 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. 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. Subsequent to March 31, 2023, we have raised $0.4 million through our equity purchase agreement. 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 $12.5 million; and commitments under various agreements for capital expenditures totaling $0.5 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 $20,000 and $7.2 million of payments under finance and operating lease obligations, respectively; and interest and principal repayment of notes payable of $19.7 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 three months ended March 31, 2023 and 2022 were as follows:

	Three Months Ended March 31,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (9,218)	$ (13,084)
Net cash provided by (used in) investing activities	4,722	(24,522)
Net cash provided by financing activities	4,588	235
Effect of foreign exchange rate changes on cash	18	13
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 110	$ (37,358)

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 $9.2 million for the three months ended March 31, 2023, which resulted from a net loss of $11.8 million, adjusted for non-cash items totaling $3.5 million and a net change in operating assets and liabilities of $(1.0) million. Significant non-cash items included (i) depreciation expense of $0.4 million related to laboratory and office equipment and leasehold improvements; (ii) non-cash lease expense of $0.1 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) stock-based compensation expense of $2.2 million; (v) accretion of debt discount of $0.3 million; (vi) non-cash interest expense of $0.1 million; and (vii) the changes in fair value of the Clene Nanomedicine and Initial Stockholders Contingent Earn-outs of $0.1 million and $7,000, 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 $0.1 million and a decrease in accounts payable of $2.4 million due to the timing of vendor invoicing and payments; (b) an increase in inventory of $45,000; (c) an increase in prepaid expenses and other current assets of $0.6 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 research and development tax credits receivable; (d) an increase in accrued liabilities of $2.1 million primarily due to increased accrued compensation and benefits and increased CRO and clinical fees; and (e) a decrease in operating lease obligations of $0.1 million.

Net cash used in operating activities was $13.1 million for the three months ended March 31, 2022, which resulted from a net loss of $13.4 million, adjusted for non-cash items totaling $2.4 million and a net change in operating assets and liabilities of $(2.1) million. Significant non-cash items included (i) stock-based compensation expense of $2.2 million; (ii) gain on termination of lease of $0.4 million; (iii) accretion of debt discount of $0.2 million; (iv) depreciation expense of $0.2 million related to laboratory and office equipment and leasehold improvements; and (v) the changes in the fair value of our (a) common stock warrant liability of $18,000 and (b) Clene Nanomedicine and Initial Stockholders Contingent Earn-outs of $0.1 million and $12,000, 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) an increase in accounts payable of $1.4 million due to the timing of vendor invoicing and payments, (B) a decrease in accrued liabilities of $2.1 million due to decreased accrued compensation and benefits, (C) an increase 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, an increase in Australia research and development credit receivable, and an increase in prepaid insurance for directors and officers, (D) an increase in operating lease obligations of $0.2 million due to our newly-leased facility in Elkton, Maryland, and our expanded facility in North East, Maryland, and (E) a decrease in accounts receivable of $49,000.

Investing Activities

Net cash provided by investing activities was $4.7 million for the three months ended March 31, 2023, which consisted of proceeds from maturities of marketable securities of $5.0 million, partially offset by purchases of property and equipment of $0.3 million. Net cash used in investing activities was $24.5 million for the three months ended March 31, 2022, which consisted of purchases of marketable securities of $23.6 million and purchases of property and equipment of $0.9 million.

Financing Activities

Net cash provided by financing activities was $4.6 million for the three months ended March 31, 2023, which consisted of (i) proceeds from issuance of common stock, net of offering costs, of $4.3 million, and (ii) proceeds from the issuance of notes payable of $0.4 million; partially offset by payments of finance lease obligations of $28,000. Net cash provided by financing activities was $0.2 million for the three months ended March 31, 2022, which consisted of proceeds from exercise of stock options of $0.3 million, partially offset by payments of finance lease obligations of $32,000.

Common Stock Sales Agreement

During the three months ended March 31, 2023, we sold 2,895,090 shares of Common Stock under our Equity Distribution Agreement (the "ATM Agreement") with Canaccord Genuity LLC, generated gross proceeds of $4.5 million, and paid commissions of $0.1 million. The issuance and sale of Common Stock 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.

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 March 31, 2023 and December 31, 2022, the unobservable inputs were as follows:

	March 31, 2023	December 31, 2022
Expected stock price volatility	115.00%	115.00%
Risk-free interest rate	3.90%	4.20%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	2.75	3.00

The change in fair value of the Clene Nanomedicine Contingent Earn-out resulted in a loss of $0.1 million and $0.1 million for the three months ended March 31, 2023 and 2022, respectively. The change in fair value of the Initial Stockholders Contingent Earn-out resulted in a loss of $7,000 and $12,000 for the three months ended March 31, 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 March 31, 2023 and December 31, 2022, the convertible note was carried at $4.9 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 March 31, 2023 and December 31, 2022, the convertible note was carried at $5.0 million and $5.0 million, respectively.

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 three months ended March 31, 2023 and 2022, the unobservable inputs were as follows:

	Three Months Ended March 31,	
	2023	2022
Expected stock price volatility	96.22% – 103.24%	89.57% – 93.07%
Risk-free interest rate	3.38% – 3.98%	1.65% – 2.02%
Expected dividend yield	0.00%	0.00%
Expected term of options (in years)	5.00 – 6.08	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 three months ended March 31, 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 March 31, 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 March 31, 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 March 31, 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 below, 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.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Although we do not currently own issued patents or pending patent applications that have been generated through the use of U.S. government funding, we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government may have certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). Such "march-in" rights can apply to new subject matter arising from the use of such government funding or grants and should not extend to pre-existing subject matter or subject matter arising from funds unrelated to the government funding or grants If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government or fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

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.

Item 6. Exhibits

Exhibit Number	Exhibit Description
3.1	Fourth Amended and Restated Certificate of Incorporation of Clene Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Registrant on May 11, 2023).
3.2	Bylaws of Clene Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Registrant on January 5, 2021).
10.1#	Purchase Agreement, dated March 3, 2023, by and between Clene Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on March 3, 2023).
10.2#	Registration Rights Agreement, dated March 3, 2023, by and between Clene Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant on March 3, 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.

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: May 12, 2023

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

Dated: May 12, 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: May 12, 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: May 12, 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 March 31, 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: May 12, 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 March 31, 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: May 12, 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.