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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

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 November 2, 2022 was 73,820,010.

CLENE INC.
Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2022

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,267	$ 50,288
Marketable securities	8,966	—
Accounts receivable	126	49
Inventory	38	41
Prepaid expenses and other current assets	5,089	4,205
Total current assets	21,486	54,583
Restricted cash	58	58
Right-of-use assets	4,707	3,250
Property and equipment, net	9,753	5,172
TOTAL ASSETS	$ 36,004	$ 63,063
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,454	$ 1,923
Accrued liabilities	2,136	3,610
Operating lease obligations, current portion	467	347
Finance lease obligations, current portion	97	146
Total current liabilities	6,154	6,026
Operating lease obligations, net of current portion	5,711	4,370
Finance lease obligations, net of current portion	45	97
Notes payable	15,726	14,484
Convertible notes payable	4,763	4,598
Common stock warrant liability	18	474
Clene Nanomedicine contingent earn-out liability	11,438	18,100
Initial Stockholders contingent earn-out liability	1,468	2,317
TOTAL LIABILITIES	45,323	50,466
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 shares authorized; 63,541,984 and 62,312,097 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	182,760	175,659
Accumulated deficit	(192,165)	(163,301)
Accumulated other comprehensive income	80	233
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(9,319)	12,597
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 36,004	$ 63,063

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 130	$ 63	$ 139	$ 400
Royalty revenue	44	47	100	124
Total revenue	174	110	239	524
Operating expenses:				
Cost of revenue	19	14	19	812
Research and development	6,403	6,146	24,149	18,893
General and administrative	3,557	4,400	12,807	16,739
Total operating expenses	9,979	10,560	36,975	36,444
Loss from operations	(9,805)	(10,450)	(36,736)	(35,920)
Other income (expense), net:				
Interest expense	(857)	80	(2,390)	(497)
Gain on extinguishment of notes payable	—	—	—	647
Gain on termination of lease	—	—	420	—
Change in fair value of common stock warrant liability	149	414	151	547
Change in fair value of Clene Nanomedicine contingent earn-out liability	(1,591)	35,042	6,662	18,072
Change in fair value of Initial Stockholders contingent earn-out liability	(205)	3,439	849	1,710
Australia research and development credit	1,346	364	2,001	1,078
Other income (expense), net	(13)	(14)	179	(13)
Total other income (expense), net	(1,171)	39,325	7,872	21,544
Net income (loss) before income taxes	(10,976)	28,875	(28,864)	(14,376)
Income tax benefit	—	69	—	213
Net income (loss)	(10,976)	28,944	(28,864)	(14,163)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	33	—	(54)	—
Foreign currency translation adjustments	(39)	(87)	(99)	(124)
Total other comprehensive loss	(6)	(87)	(153)	(124)
Comprehensive income (loss)	$ (10,982)	$ 28,857	$ (29,017)	$ (14,287)
Net income (loss) per share (Note 16)				
Basic	$ (0.17)	$ 0.47	$ (0.46)	$ (0.23)
Diluted	$ (0.17)	$ 0.42	$ (0.46)	$ (0.23)
Weighted average common shares outstanding (Note 16)				
Basic	63,508,928	62,071,754	63,234,757	61,307,699
Diluted	63,508,928	70,038,634	63,234,757	61,307,699

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	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balances at December 31, 2021	62,312,097	$ 6	$ 175,659	$ (163,301)	$ 233	$ 12,597
Reclassification of common stock warrant liability to equity	—	—	305	—	—	305
Exercise of stock options	934,448	—	267	—	—	267
Stock-based compensation expense	—	—	2,202	—	—	2,202
Unrealized loss on available-for-sale securities	—	—	—	—	(50)	(50)
Foreign currency translation adjustment	—	—	—	—	50	50
Net loss	—	—	—	(13,354)	—	(13,354)
Balances at March 31, 2022	63,246,545	$ 6	$ 178,433	$ (176,655)	$ 233	$ 2,017
Exercise of stock options	110,000	—	17	—	—	17
Stock-based compensation expense	—	—	2,184	—	—	2,184
Issuance of common stock upon vesting of restricted stock awards	65,363	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	—	(37)	(37)
Offering costs	—	—	(100)	—	—	(100)
Foreign currency translation adjustment	—	—	—	—	(110)	(110)
Net loss	—	—	—	(4,534)	—	(4,534)
Balances at June 30, 2022	63,421,908	$ 6	$ 180,534	$ (181,189)	$ 86	$ (563)
Issuance of common stock, net of issuance costs	40,000	—	128	—	—	128
Stock-based compensation expense	—	—	2,098	—	—	2,098
Issuance of common stock upon vesting of restricted stock awards	80,076	—	—	—	—	—
Unrealized gain on available-for-sale securities	—	—	—	—	33	33
Foreign currency translation adjustment	—	—	—	—	(39)	(39)
Net loss	—	—	—	(10,976)	—	(10,976)
Balances at September 30, 2022	63,541,984	$ 6	$ 182,760	$ (192,165)	$ 80	$ (9,319)
Balances at December 31, 2020	59,526,171	6	153,571	(153,561)	325	341
Exercise of stock options	48,211	—	50	—	—	50
Stock-based compensation expense	—	—	3,265	—	—	3,265
Foreign currency translation adjustment	—	—	—	—	24	24
Net loss	—	—	—	(39,756)	—	(39,756)
Balances at March 31, 2021	59,574,382	$ 6	$ 156,886	$ (193,317)	$ 349	$ (36,076)
Issuance of common stock upon the private offering	960,540	—	9,250	—	—	9,250
Exercise of stock options	124,680	—	58	—	—	58
Stock-based compensation expense	—	—	4,255	—	—	4,255
Issuance of common stock upon vesting of restricted stock awards	21,989	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	(61)	(61)
Net loss	—	—	—	(3,351)	—	(3,351)
Balances at June 30, 2021	60,681,591	$ 6	$ 170,449	$ (196,668)	$ 288	$ (25,925)
Exercise of stock options	236,976	—	319	—	—	319
Exercise of warrants	1,002,250	—	10	—	—	10
Exercise of underwriter's option	54,083	—	—	—	—	—
Stock-based compensation expense	—	—	2,425	—	—	2,425
Issuance of common stock upon vesting of restricted stock awards	202,120	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	(87)	(87)
Net income	—	—	—	28,944	—	28,944
Balances at September 30, 2021	62,177,020	$ 6	$ 173,203	$ (167,724)	$ 201	$ 5,686

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (28,864)	$ (14,163)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	715	734
Non-cash lease expense	285	81
Change in fair value of common stock warrant liability	(151)	(547)
Change in fair value of Clene Nanomedicine contingent earn-out liability	(6,662)	(18,072)
Change in fair value of Initial Stockholders contingent earn-out liability	(849)	(1,710)
Stock-based compensation expense	6,484	9,945
Gain on extinguishment of notes payable	—	(647)
Gain on termination of lease	(420)	—
Loss on sale of marketable securities	2	—
Accretion of debt discount	661	—
Non-cash interest expense	83	(134)
Changes in operating assets and liabilities:		
Accounts receivable	(77)	(48)
Inventory	3	150
Prepaid expenses and other current assets	(884)	(1,230)
Accounts payable	213	446
Accrued liabilities	(1,474)	511
Deferred income tax	—	(192)
Operating lease obligations	(360)	(142)
Net cash used in operating activities	(31,295)	(25,018)
Cash flows from investing activities:		
Purchases of marketable securities	(24,582)	—
Proceeds from maturity of marketable securities	8,000	—
Proceeds from sale of marketable securities	7,614	—
Purchases of property and equipment	(3,478)	(661)
Net cash used in investing activities	(12,446)	(661)
Cash flows from financing activities:		
Proceeds from exercise of stock options	284	427
Proceeds from warrants exercised	—	10
Proceeds from at-the-market offering	132	—
Payments of at-the-market offering commissions	(4)	—
Payments of finance lease obligations	(101)	(117)
Proceeds from the issuance of notes payable	694	20,000
Payments of debt issuance costs	(30)	(534)
Payments of notes payable	—	(5)
Proceeds from the private placement	—	9,250
Payment of deferred offering costs	(100)	(1,901)
Net cash provided by financing activities	875	27,130
Effect of foreign exchange rate changes on cash and restricted cash	(155)	(116)
Net increase (decrease) in cash, cash equivalents and restricted cash	(43,021)	1,335
Cash, cash equivalents and restricted cash – beginning of period	50,346	59,275
Cash, cash equivalents and restricted cash – end of period	$ 7,325	$ 60,610
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	7,267	60,552
Restricted cash	58	58
Cash, cash equivalents and restricted cash	$ 7,325	$ 60,610
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	$ 2,492
Lease incentive realized	$ 500	$ —
Lease liability settled through termination of lease	$ 602	$ —
Reclassification of common stock warrant liability to permanent equity	$ 305	$ —
Purchases of property and equipment in accounts payable	$ 1,318	$ —
Common stock warrant liability recorded at issuance of notes payable	$ —	$ 1,457
Supplemental cash flow information:		
Cash paid for interest expense	$ 1,646	$ 631

See accompanying notes to the condensed consolidated financial statements.

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 in neurology, infectious disease, and oncology. Our efforts are currently focused on addressing the high unmet medical needs in two areas: first, those related to central nervous system disorders including Amyotrophic Lateral Sclerosis ("ALS"), Multiple Sclerosis ("MS"), and Parkinson's Disease ("PD"); and second, those related to COVID-19, a highly infectious viral respiratory disease with serious and sometimes fatal co-morbidities. 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 17).

Going Concern

We incurred a loss from operations of $9.8 million and $10.5 million for the three months ended September 30, 2022 and 2021, respectively; and $36.7 million and $35.9 million for the nine months ended September 30, 2022 and 2021, respectively. Our accumulated deficit was $192.2 million and $163.3 million as of September 30, 2022 and December 31, 2021, respectively. Our cash, cash equivalents, and marketable securities totaled $16.2 million and $50.3 million as of September 30, 2022 and December 31, 2021, respectively, and net cash used in operating activities was $31.3 million and $25.0 million for the nine months ended September 30, 2022 and 2021, 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.

Our management performs strategic reviews of our operating plans and budgets, considering the status of our product development programs, human capital, capital needs and resources, and current capital market conditions. Based on these reviews, our Board of Directors (the "Board") and management make adjustments to our operating plans and budgets to allocate our projected cash expenditures. Notwithstanding these ongoing adjustments, we project 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, and we must obtain additional financing. Additionally, pursuant to our term loan with Avenue Venture Opportunities Fund, L.P. ("Avenue"), we must maintain unrestricted cash and cash equivalents of at least $5.0 million to avoid acceleration of the full balance of the loan. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

To mitigate our funding needs, we intend to implement plans to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as potentially utilizing additional funds available under our term loan with Avenue, subject to certain contingent conditions (see Note 9), as well as our existing at-the-market facility. 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. In October 2022, we announced an equity offering which provided net cash proceeds of $10.8 million. We are also in the process of implementing cost-saving initiatives, including potentially delaying or 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

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the COVID-19 outbreak. The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the COVID-19 pandemic and its effects on our business and operations remains uncertain. 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 have affected our ability to initiate and complete preclinical studies, caused manufacturing disruptions, and created delays at clinical trial site initiation and clinical trial enrollment, leading to the early conclusion of an ongoing clinical trial. The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds to support our operations. Moreover, the COVID-19 pandemic has significantly impacted economies worldwide and could result in adverse effects on our business and operations.

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 certain 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 and we are not aware of any specific related event or circumstance that would require us to revise the estimates reflected in these 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 and 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. ("Clene Nanomedicine"), a subsidiary incorporated in Delaware, Clene Australia Pty Ltd ("Clene Australia"), a subsidiary incorporated in Australia, Clene Netherlands B.V. ("Clene Netherlands"), a subsidiary incorporated in the Netherlands, and dOrbital, Inc., a subsidiary incorporated in Delaware, after elimination of all intercompany accounts and transactions. We have prepared the accompanying condensed consolidated financial statements in accordance with United States ("U.S.") Generally Accepted Accounting Principles ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. The condensed consolidated financial statements have been prepared on the same basis as our audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The financial data and other information disclosed in the condensed consolidated financial statements and related notes for the three and nine months ended September 30, 2022 and 2021 are unaudited.

Results of operations for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of the results for the entire fiscal year or any other period. The condensed consolidated financial statements for the three and nine months ended September 30, 2022 and 2021 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 mainly held in financial institutions. 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 and investments are classified as current and noncurrent in 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 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 (loss) 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 $24,000 in raw materials and $14,000 in finished goods as of September 30, 2022, and $26,000 in raw material and $15,000 in finished goods as of December 31, 2021. Inventory primarily 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 income (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.

Contingent Earn-Out Liabilities

In connection with the Reverse Recapitalization, certain stockholders are entitled to receive additional shares of Clene Inc. common stock, par value $0.0001 ("Common Stock") (the "Contingent Earn-outs") upon us achieving certain milestones (see Note 3). In accordance with Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging* ("ASC 815"), the Contingent Earn-outs are not indexed to our own stock and therefore are accounted for as a liability at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value 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, *Distinguishing Liabilities from Equity* ("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, as of each subsequent quarterly 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*.

We recognize grant funding without conditions or continuing performance obligations, including the Australia research and development credit, as other income in the condensed consolidated statements of operations and comprehensive income (loss). We accrue the Australia research and development credit receivable in other current assets (see Note 5) 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 income (loss). After submission of our Australia tax return, we receive a cash refund of the Australia research and development credit 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 income (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 recorded grants as a reduction of research and development expenses of $0 and $0 for the three months ended September 30, 2022 and 2021, respectively; and $0 and $0.2 million for the nine months ended September 30, 2022 and 2021, respectively.

Foreign Currency Translation and Transactions

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

Adjustments resulting from the translation of the condensed consolidated financial statements of our foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' equity.

We also incur foreign exchange transaction gains and losses for purchases denominated in foreign currencies. Foreign exchange transaction gains and losses are included in other income (expense), net, as incurred.

Comprehensive Income (Loss)

Comprehensive income (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 income (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 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.

Stock-based compensation expense is recognized at fair value. 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 the Nasdaq Capital Market ("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 May 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging —Contracts in Entity's Own Equity (Subtopic 815-40)*. The amendments in this update relate to the recognition and measurement of earnings per share for certain modifications or exchanges of equity-classified written call options or warrants. The guidance was effective for our fiscal year and interim periods within our fiscal year beginning after December 15, 2021. The adoption of this guidance did not have an impact on our condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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 is effective for our fiscal years beginning after December 15, 2022. We are currently evaluating the expected impact, if any, of the new guidance as a result of this extended deadline of implementation for smaller reporting companies.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*. The amendments in this update add disclosure requirements for transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy, including disclosure about the nature of the transactions, accounting policy, affected line items in the balance sheet and income statement, amounts applicable to each financial statement line item, and significant terms and conditions of the transactions including commitments and contingencies. The guidance is effective for all entities for financial statements issued for annual periods beginning after December 15, 2021, with early adoption permitted. We are currently evaluating the expected impact, if any, of the new guidance.

Note 3. Reverse Recapitalization with Tottenham and Clene Nanomedicine

On December 30, 2020 (the "Closing Date"), Chelsea Worldwide Inc., our predecessor, consummated the Reverse Recapitalization by and among Clene Nanomedicine, Tottenham Acquisition I Limited ("Tottenham"), Chelsea Worldwide Inc. ("PubCo"), a Delaware corporation and wholly-owned subsidiary of Tottenham, Creative Worldwide Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of PubCo, and Fortis Advisors LLC, a Delaware limited liability company as the representative of our stockholders. The Reverse Recapitalization was effected in two steps: (i) Tottenham was reincorporated to the state of Delaware by merging with and into PubCo (the "Reincorporation Merger"); and (ii) promptly following the Reincorporation Merger, Merger Sub was merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine becoming a wholly-owned subsidiary of PubCo (the "Acquisition Merger"). On the Closing Date, PubCo changed its name from Chelsea Worldwide Inc. to Clene Inc. and listed its shares of Common Stock, par value $0.0001 per share on Nasdaq under the symbol "CLNN."

We received gross proceeds of $9.4 million from the Reverse Recapitalization and incurred offering costs of $5.9 million, which excludes the fair value of Common Stock issued as payment of certain offering costs, resulting in net proceeds of $3.5 million. We paid LifeSci Capital LLC, an advisor to Clene Nanomedicine, 644,164 shares of Common Stock as consideration for its services.

The transaction was accounted for as a "reverse recapitalization" in accordance with GAAP. Under this method of accounting, Tottenham was treated as the "acquired" company for financial reporting purposes. This determination was primarily based on the fact that subsequent to the Reverse Recapitalization, Clene Nanomedicine's stockholders have a majority of the voting power of the Company, Clene Nanomedicine comprises all of the ongoing operations of the Company, Clene Nanomedicine comprises a majority of the governing body of the Company, and Clene Nanomedicine's senior management comprises all of the senior management of the Company. Accordingly, for accounting purposes, this transaction was treated as the equivalent of Clene Nanomedicine issuing shares for the net assets of Tottenham, accompanied by a recapitalization.

Earn-Out Shares

Certain of Clene Nanomedicine's stockholders are entitled to receive earn-out shares (the "Clene Nanomedicine Contingent Earn-out") as follows : (i) 3,333,333 shares of Common Stock if (a) the volume-weighted average price ("VWAP") of the shares 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 closing 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) 2,500,000 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 closing of the Reverse Recapitalization (the requirements in (a) and (b) collectively, "Milestone 2"); and (iii) 2,500,000 shares of Common Stock if Clene Nanomedicine completed a randomized placebo-controlled clinical trial for treatment of COVID-19 which results in a statistically significant finding of clinical efficacy within twelve months of the closing of the Reverse Recapitalization ("Milestone 3"), which was not achieved. If Milestone 1 is not achieved but Milestone 2 is achieved, the Clene Nanomedicine stockholders will receive an issuance equal to the shares issued upon satisfaction of Milestone 1. As of the Closing Date, the Clene Nanomedicine Contingent Earn-out shares increased to 8,346,185 shares of Common Stock due to exercises of stock options during November 2020.

Tottenham's former officers and directors, sponsor, and public stockholders (the "Initial Stockholders") may be entitled to receive earn-out shares as follows (the "Initial Stockholders Contingent Earn-out"): (i) 375,000 shares of Common Stock upon satisfaction of the requirements of Milestone 1; and (ii) 375,000 shares of Common Stock upon satisfaction of the requirements of Milestone 2. If Milestone 1 is not achieved but Milestone 2 is achieved, the Initial Stockholders will receive an issuance equal to the shares issued upon satisfaction of Milestone 1.

The Contingent Earn-outs shares have been classified as liabilities in the condensed consolidated balance sheets and are remeasured to fair value at each reporting date. We did not achieve Milestone 3 and the 2,503,851 Milestone 3 Contingent Earn-out shares were cancelled as of December 31, 2021.

Note 4. Marketable Securities

Available-for-Sale Securities

Available-for-sale securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) until realized. Available-for-sale securities as of September 30, 2022 were as follows:

	September 30, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 4,984	$ —	$ (37)	$ 4,947
Corporate debt securities	4,036	—	(17)	4,019
Total	$ 9,020	$ —	$ (54)	$ 8,966

As of December 31, 2021, there were no outstanding available-for-sale securities. Proceeds from the sale and maturity of available-for-sale securities were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Proceeds from maturity of marketable securities	$ 5,500	$ —	$ 8,000	$ —
Proceeds from sale of marketable securities	$ 4,597	—	$ 7,614	—
Total	$ 10,097	$ —	$ 15,614	$ —

Realized gains and losses included in earnings from the sale of available-for-sale securities were insignificant. All available-for-sale securities had a contractual maturity within one year. As of September 30, 2022, we did not have any allowance for credit losses or impairments of available-for-sale securities.

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of September 30, 2022 and December 31, 2021 were as follows:

(in thousands)	September 30, 2022	December 31, 2021
Australia research and development credit receivable	$ 1,598	$ 1,564
Metals to be used in research and development	2,493	2,237
Other	998	404
Total prepaid expenses and other current assets	$ 5,089	$ 4,205

Note 6. Property and Equipment, Net

Property and equipment, net, as of September 30, 2022 and December 31, 2021 were as follows:

(in thousands)	September 30, 2022	December 31, 2021
Lab equipment	$ 3,410	$ 3,327
Office equipment	177	147
Computer software	459	—
Leasehold improvements	3,956	3,943
Construction in progress	6,684	2,052
	14,686	9,469
Less accumulated depreciation	(4,933)	(4,297)
Total property and equipment, net	$ 9,753	$ 5,172

Depreciation expense recorded in research and development expense and general and administrative expense for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
General and administrative	$ 67	$ 29	$ 163	$ 86
Research and development	166	206	552	648
Total depreciation expense	$ 233	$ 235	$ 715	$ 734

Note 7. Accrued Liabilities

Accrued liabilities as of September 30, 2022 and December 31, 2021 were as follows:

(in thousands)	September 30, 2022	December 31, 2021
Accrued compensation and benefits	$ 764	$ 2,049
Accrued CRO and clinical fees	744	718
Deferred grant funds	520	520
Other	108	323
Total accrued liabilities	$ 2,136	$ 3,610

Note 8. 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

In September 2021, we commenced an operating lease for laboratory space and recorded a right-of-use asset of $2.4 million and lease liability of $2.4 million, net of a lease incentive of $1.0 million which represents an allowance from the lessor for facility alterations. As the lease incentive is payable based on events within our control and are deemed reasonably certain to occur, we recorded the lease incentive as a reduction of the right-of-use asset and lease liability at the lease commencement. As of September 30, 2022 and December 31, 2021, we incurred $1.0 million and $0.5 million, respectively, of costs related to the lease incentive which we recorded as construction in progress, with a corresponding increase to the lease liability, and the construction in progress will be capitalized as leasehold improvements when the facility is placed into service. The lease has an initial ten-year term and provides us the right and option to extend or renew for two periods of five years each. In accordance with ASC 842, *Leases*, the payments to be made in option periods have not been recognized as part of the right-of-use asset or lease liability because we do not assess the exercise of the option to be reasonably certain.

In February 2022, we commenced an operating lease for existing laboratory space and recorded a right-of-use asset of $2.3 million and lease liability of $2.3 million and terminated the previous right-of-use asset of $0.6 million and lease liability of $1.0 million. We

recorded a gain on termination of lease of $0.4 million in the condensed consolidated statements of operations and comprehensive income (loss) for the nine months ended September 30, 2022.

Our right-of-use assets pertain to operating leases. As of September 30, 2022 and December 31, 2021, our operating lease obligations had a weighted-average discount rate of 9.6% and 9.6%, respectively, and a weighted-average remaining term of 7.5 years and 8.1 years, respectively.

Finance Leases

Assets recorded under finance lease obligations and included with property and equipment as of September 30, 2022 and December 31, 2021 were as follows:

(in thousands)	September 30, 2022	December 31, 2021
Lab equipment	$ 408	$ 408
Work in process	228	228
Total	636	636
Less accumulated depreciation	(305)	(244)
Net	$ 331	$ 392

As of September 30, 2022 and December 31, 2021, our finance lease obligations had a weighted-average interest rate of 9.6% and 8.8%, respectively, and a weighted-average remaining term of 1.3 years and 1.9 years, respectively.

Maturity Analysis of Leases

The maturity analysis of our finance and operating leases as of September 30, 2022 was as follows:

(in thousands)	Finance Leases	Operating Leases
2022 (remainder)	$ 37	$ 188
2023	96	1,145
2024	27	1,171
2025	—	1,202
2026	—	1,231
2027	—	1,129
Thereafter	—	2,786
Total undiscounted cash flows	160	8,852
Less amount representing interest/discounting	(18)	(2,674)
Present value of future lease payments	142	6,178
Less lease obligations, current portion	(97)	(467)
Lease obligations, long term portion	$ 45	$ 5,711

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

Components of Lease Cost

The components of finance and operating lease costs for the three and nine months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Finance lease costs:				
Amortization	$ 20	$ 37	$ 61	$ 110
Interest on lease liabilities	6	6	12	21
Operating lease costs	256	107	695	247
Short-term lease costs	—	98	—	214
Variable lease costs	65	32	238	71
Total lease costs	$ 347	$ 280	$ 1,006	$ 663

Supplemental Cash Flow Information

(in thousands)	Nine Months Ended September 30, 2022	2021
Operating cash flows from operating leases	$ (933)	$ (533)
Operating cash flows from finance leases	$ (12)	$ (21)
Financing cash flows from finance leases	$ (101)	$ (117)

Note 9. Notes Payable

Our long-term debt, net of original issue discount and unamortized debt issuance costs, as of September 30, 2022 and December 31, 2021 was as follows:

(in thousands, except interest rates)	Stated Interest Rate	September 30, 2022	December 31, 2021
Maryland DHCD (commenced 2019)	8.00%	$ 644	$ 614
Maryland DHCD (commenced 2022)	6.00%	694	—
Advance Cecil, Inc. (commenced 2019)	8.00%	128	122
Avenue Venture Opportunities Fund, L.P. (commenced 2021)	12.85%	20,000	20,000
		21,466	20,736
Less unamortized debt issuance costs and original issue discounts		(977)	(1,654)
Less convertible notes payable, net of unamortized debt discount and issuance costs		(4,763)	(4,598)
Total notes payable		$ 15,726	$ 14,484

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. The agreement provides for a term loan of $0.5 million bearing simple interest at an annual rate of 8.00%. We are subject to affirmative and negative covenants until maturity, including providing information about the Company and our operations; 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. There are no financial covenants associated with the 2019 MD Loan. We are not in violation of any covenants. The 2019 MD Loan established "Phantom Shares" at issuance 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 the balance of principal plus accrued interest or the value of the Phantom Shares. The value of the Phantom Shares is based on the closing price of our Common Stock on Nasdaq at the end of each reporting period. As of September 30, 2022 and December 31, 2021, the note was recorded at principal plus accrued interest in the condensed consolidated balance sheets. We recognized interest expense of $10,000 and $30,000 for the three and nine months ended September 30, 2022, respectively; and interest income of $0.5 million and $0.3 million for the three and nine months ended September 30, 2021, 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 the production of pharmaceutical drugs. As of September 30, 2022, we had drawn $0.7 million under the term loan, with the remainder available upon our submission of disbursement requests to purchase the Assets. The 2022 MD Loan matures on July 1, 2027 (the "Maturity Date"). The first twelve payments, commencing on July 1, 2022, are deferred. Immediately thereafter, there shall be eighteen monthly installments of interest-only based on the actual amount advanced under the loan, each up to a maximum amount of $15,000; followed by thirty monthly installments of principal and interest, each in the amount of $33,306, which is due and payable even if the entire loan has not been advanced prior to the date such monthly payment is due and payable, with a balloon payment of all accrued and unpaid interest and principal due on the Maturity Date. We recorded $31,000 of debt issuance costs that are being amortized over the contractual term using the effective interest method. Pursuant to the 2022 MD Loan, DHCD was granted a continuing security interest in the Assets as collateral. Under a priority of liens agreement by and between DHCD and Avenue, an existing secured creditor of the Company, DHCD's continuing security interest in the Assets shall be a first priority lien. We recognized interest expense of $10,000 and $12,000 for the three and nine months ended September 30, 2022, respectively.

Advance Cecil Inc. 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. The agreement provides for a term loan of $0.1 million bearing simple interest at an annual rate

of 8.00%. We are subject to affirmative covenants until maturity, including providing information about the Company and our operations. There are no financial covenants associated with the 2019 Cecil Loan. We are not in violation of any covenants. The 2019 Cecil Loan established "Phantom Shares" at issuance 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 the balance of principal plus accrued interest or the value of the Phantom Shares. The value of the Phantom Shares is based on the closing price of our Common Stock on Nasdaq at the end of each reporting period. As of September 30, 2022 and December 31, 2021, the note was recorded at principal plus accrued interest in the condensed consolidated balance sheets. We recognized interest expense of $2,000 and $6,000 for the three and nine months ended September 30, 2022, respectively; and interest income of $106,000 and $52,000 for the three and nine months ended September 30, 2021, respectively.

PPP Loan

In May 2020, we entered into a note payable in the amount of $0.6 million (the "PPP Loan") under the Paycheck Protection Program of the CARES Act. The Paycheck Protection Program permits forgiveness of amounts loaned for payments of payroll and other qualifying expenses, subject to certain conditions. In January 2021, the full balance of the PPP Loan was forgiven and we recorded a gain on extinguishment of notes payable for the nine months ended September 30, 2021.

Avenue Loan

In May 2021, we entered into a loan agreement (the "2021 Avenue Loan") with Avenue. The agreement provides for a 42-month term loan of up to $30.0 million. The first tranche is $20.0 million ("Tranche 1"), of which $15.0 million was funded at close and $5.0 million was funded in September 2021. We incurred issuance costs of $0.6 million of which $46,951 was expensed immediately. The remaining unfunded tranche of $10.0 million ("Tranche 2") is available until December 31, 2022. Funding of Tranche 2 is subject to (a) our receipt of $5.0 million financing through the state of Maryland; (b) our achievement of a statistically significant result in certain clinical trials ("Performance Milestone 1"); (c) our receipt of net proceeds of at least $30.0 million from the sale and issuance of our equity securities between May 2, 2021 and December 31, 2022; and (d) mutual agreement of us and Avenue. The 2021 Avenue Loan bears interest at a variable rate equal to the sum of (i) the greater of (a) the prime rate or (b) 3.25%, plus (ii) 6.60%. As of September 30, 2022 and December 31, 2021, the interest rate was 12.85% and 9.85%, respectively. Payments are interest-only for the first 12 months and have been extended an additional 12 months (the "First Interest-only Period Extension") based on our achievement of Performance Milestone 1. Payments may be extended up to 36 months if we (i) achieve the First Interest-only Period Extension and (b) draw from Tranche 2. The loan principal will amortize equally from the end of the interest period to the expiration of the 42-month term on December 1, 2024. On the maturity date, an additional payment equal to 4.25% of the funded loans, currently equal to $0.9 million (the "Final Payment"), is due in addition to the remaining unpaid principal and accrued interest. The Final Payment was recorded as a debt premium and is being amortized over the contractual term using the effective interest method. The Final Payment is related to the loan host and is not bifurcated pursuant to ASC 815. We are subject to affirmative and negative covenants until maturity in the absence of prepayments, including providing information about the Company and our operations; limitation on our ability to retire, repurchase, or redeem our Common Stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. Also pursuant to the 2021 Avenue Loan, we are required to maintain unrestricted cash and cash equivalents of at least $5.0 million, provided that upon our (i) achievement of Performance Milestone 1, and (ii) receiving of net proceeds of at least $30.0 million from the sale and issuance of our equity securities, we shall no longer be subject to financial covenants. We are not in violation of any covenants. Avenue also has the ability to make all obligations under the 2021 Avenue Loan immediately due and payable upon occurrence of certain events of default or material adverse effects, as outlined in the loan agreement. 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.

Pursuant to the agreement, we granted Avenue a warrant to purchase 115,851 shares of Common Stock (the "Avenue Warrant") at an exercise price of $8.63 per share. Upon the funding of Tranche 2, the Avenue Warrant shall be adjusted to include an additional estimated 184,133 shares of Common Stock, which is equal to 5% of the principal amount of Tranche 2, divided by the five (5)-day VWAP per share as of the end of trading on the last trading day before the issuance of Tranche 2. We accounted for the Tranche 2 contingently-issuable warrant at inception of the 2021 Avenue Loan in accordance with ASC 815 and the fair value and issuable shares are remeasured at each reporting period.

Avenue has the right, in its discretion, but not the obligation, at any time between May 21, 2022 through May 21, 2024, while the loan is outstanding, to convert up to $5.0 million of principal into Common Stock (the "Conversion Feature") at a price per share equal to 120% of the Avenue Warrant exercise price. Exercise of the Conversion Feature is subject to certain minimum price and volume conditions of our Common Stock on Nasdaq. The Conversion Feature did not meet the requirements for separate accounting and is not accounted for as a derivative instrument. The number of shares of Common Stock contingently issuable upon conversion is 482,703 shares. We classified $5.0 million of the 2021 Avenue Loan as convertible notes payable as of September 30, 2022 and December 31, 2021, with unamortized debt discount and issuance costs of $0.2 million and $0.4 million, respectively. For the convertible notes payable

for the three and nine months ended September 30, 2022, we recognized (i) total interest expense of $0.2 million and $0.6 million, respectively; (ii) coupon interest expense of $0.2 million and $0.4 million, respectively; and (iii) amortization of debt discount and issuance costs of $0.1 million and $0.2 million, respectively; and the effective interest rate was 18.41%. For the three and nine months ended September 30, 2021, we recognized (i) total interest expense of $0.2 million and $0.3 million, respectively; (ii) coupon interest expense of $0.1 million and $0.2 million, respectively; and (iii) amortization of debt discount and issuance costs of $41,000 and $64,000, respectively; and the effective interest rate was 15.46%.

The net proceeds from the issuance of the loan were initially allocated to the warrant at an amount equal to their fair value of $1.5 million and the remainder to the loan. The allocation of incurred financing costs of $0.5 million, which together with the fair value of the Avenue Warrant and the Final Payment, are recorded as a debt discount and debt premium, respectively, and are being amortized over the contractual term using the effective interest method. We recognized interest expense of $0.8 million and $2.3 million for the three and nine months ended September 30, 2022, respectively; and interest expense of $0.6 million and $0.8 million for the three and nine months ended September 30, 2021, respectively.

Future principal payments under the 2021 Avenue Loan, net of unamortized debt discounts, if Avenue does not exercise the Conversion Feature, and under the 2022 MD Loan, net of unamortized debt discounts, are as follows:

(in thousands)	2021 Avenue Loan	2022 MD Loan
2022 (remainder)	$ —	$ —
2023	6,667	—
2024	13,333	—
2025	—	369
2026	—	313
2027	—	—
Thereafter	—	—
Subtotal of future principal payments	20,000	682
Accrued and unpaid interest	—	13
Less unamortized debt issuance costs and original issue discounts	(948)	(29)
Total	$ 19,052	$ 666

Note 10. Common Stock Warrants

As of September 30, 2022 and December 31, 2021, outstanding warrants to purchase shares of Common Stock were as follows:

Date Exercisable	Number of Shares Issuable		Exercise Price	Exercisable for	Classification	Expiration
December 2020	2,407,500	(1)	$ 11.50	Common Stock	Equity	December 2025
December 2020	24,583	(2)	$ 11.50	Common Stock	Equity	December 2025
December 2020	1,929,111	(3)	$ 1.97	Common Stock	Equity	April 2023
May 2021	115,851	(4)	$ 8.63	Common Stock	Equity	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 September 30, 2022 and December 31, 2021, 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 Chardan Capital Markets, LLC ("Chardan") upon exercise of their unit purchase option, which was issued in connection with Tottenham's initial public offering. As of September 30, 2022 and December 31, 2021, 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 September 30, 2022 and December 31, 2021, no warrants had been exercised.

(4) Consists of 115,851 shares of Common Stock underlying the Avenue Warrant. As of September 30, 2022 and December 31, 2021, the warrant had not been exercised.

Note 11. 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 September 30, 2022 and December 31, 2021, we had commitments under various agreements for capital expenditures totaling $1.7 million and $0.6 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 approximately $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 September 30, 2022, 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 12. Income Taxes

We have not recorded income tax benefits for the net operating losses incurred during the three and nine months ended September 30, 2022 and 2021 or for research and development tax credits or other deferred tax assets due to uncertainty of realizing benefits from these items.

The components of loss before income taxes for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
United States	$ (9,432)	$ 29,860	$ (25,787)	$ (11,435)
Foreign	(1,544)	(985)	(3,077)	(2,941)
Income (loss) before provision for income taxes	$ (10,976)	$ 28,875	$ (28,864)	$ (14,376)

We are subject to taxation in the U.S., Australia, Netherlands, and various state jurisdictions. Our tax returns from 2015 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 adjusts 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 13. Benefit Plans

401(k) Plan

Our 401(k) plan is a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) plan, participating U.S. employees may defer a portion of their pretax earnings, up to the U.S. Internal Revenue Service annual contribution limit. 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 $34,000 and $28,000 for the three months ended September 30, 2022 and 2021, respectively, and $0.2 million and $0.1 million for the nine months ended September 30, 2022 and 2021, respectively.

2020 Stock Plan

The 2020 Stock Plan reserves 12,000,000 shares of Common Stock for issuance thereunder, all of which may be issued pursuant to incentive stock options or any other type of award under the 2020 Stock Plan. Selected employees, officers, directors, and consultants of the Company are eligible to participate in the 2020 Stock Plan. The purpose of the 2020 Stock Plan is to enable us to offer competitive equity compensation packages in order to attract and retain talent and align the interests of management with those of stockholders. The 2020 Stock Plan is administered by the Board. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the Board, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the Common Stock on the date of grant. Stock options expire ten years after the grant date unless the Board sets a shorter term. Stock options granted to employees, officers, directors, and consultants generally vest over a four-year period. If an option or award granted under the 2020 Stock Plan expires, or is terminated, forfeited, repurchased, or cancelled, the unissued shares subject to that option or award shall again be available under the 2020 Stock Plan. As of September 30, 2022, the Board has granted a total of 7,683,138 stock options and rights to restricted stock awards under the 2020 Stock Plan, and 4,316,862 shares remained available for future grant.

2014 Stock Plan

The 2014 Stock Plan is administered by the Board. Stock options granted under the 2014 Stock Plan expire ten years after the grant date. Stock options and restricted stock awards granted to employees, officers, directors, and consultants generally vest over a four-year period. Effective as of the closing of the Reverse Recapitalization, no additional awards may be granted under the 2014 Stock Plan and as a result, if any award granted under the 2014 Stock Plan expires, or is terminated, forfeited, repurchased, cancelled, or tendered by a participant to us to exercise an award, the unissued shares subject to that award will not be available for future awards.

Stock-Based Compensation Expense

Stock-based compensation expense recorded in research and development expense and general and administrative expense for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
General and administrative	$ 1,247	$ 1,567	$ 4,056	$ 6,084
Research and development	851	858	2,428	3,861
Total stock-based compensation expense	$ 2,098	$ 2,425	$ 6,484	$ 9,945

Stock-based compensation expense by award type for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Stock options	$ 2,098	$ 1,583	$ 6,484	$ 3,096
Restricted stock awards	—	842	—	6,849
Total stock-based compensation expense	$ 2,098	$ 2,425	$ 6,484	$ 9,945

Stock Options

Outstanding stock options and related activity for the nine months ended September 30, 2022 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, 2021	10,395,027	3.35	6.32	$ 21,082
Granted	2,865,411	3.01	9.41	—
Exercised	(1,044,448)	0.27	—	2,641
Forfeited	(42,420)	5.06	—	—
Outstanding – September 30, 2022	12,173,570	$ 3.53	6.75	$ 10,225
Vested and exercisable – September 30, 2022	6,529,233	$ 2.33	4.81	$ 10,120
Vested, exercisable or expected to vest – September 30, 2022	12,173,570	$ 3.53	6.75	$ 10,225

As of September 30, 2022 and December 31, 2021, we had approximately $18.1 million and $18.3 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 2.62 years and 3.05 years, respectively.

Stock options are valued using a Black-Scholes option-pricing model. Due to the limited trading history of our Common Stock, the expected volatility is derived from the average historical stock volatilities of several unrelated comparable public companies within our industry, over a period equivalent to the expected term of the stock option grants. The risk-free interest rate for periods within the contractual life of the stock options is based on the U.S. Treasury yield curve in effect on the grant date. The expected dividend is assumed to be zero as we have never paid a dividend and have no plans to do so. The expected term represents the period the stock options are expected to be outstanding. For stock options that are considered to be in the ordinary course, we determine the expected term using the simplified method, which considers the term to be the average of the time-to-vesting and the contractual life of the stock options. For other stock option grants, we estimate the expected term using historical data on employee exercises and post-vesting employment termination behavior, while also considering the contractual life of the award.

The assumptions used to calculate the fair value of stock options granted during the nine months ended September 30, 2022 and 2021 were as follows:

	Nine Months Ended September 30,	
	2022	2021
Expected stock price volatility	89.57% – 98.13%	84.80% – 87.40%
Risk-free interest rate	1.65% – 3.00%	0.59% – 0.94%
Expected dividend yield	0.00%	0.00%
Expected term of options	5.00 – 6.98 years	6.00 years

The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2022 and 2021 was $2.24 and $8.85, respectively.

Restricted Stock Awards

In connection with the Reverse Recapitalization, the following outstanding and unvested rights to restricted stock awards were granted to various employees and non-employee directors:

- 454,781 shares which are eligible to vest based on certain market conditions, subject to the holder's continuous employment through such vesting date. The award complements the Milestone 1 earn-out share entitlement of Clene Nanomedicine stockholders and vests based on the same market condition (see Note 3). The grant-date fair value of these awards, using a Monte Carlo valuation model, was $4.3 million. Based on the outcome of the market condition as of the September 30, 2022 and December 31, 2021 measurement dates, no shares were vested.
- 341,090 shares which are eligible to vest based on certain market conditions, subject to the holder's continuous employment through such vesting date. The award complements the Milestone 2 earn-out share entitlement of Clene Nanomedicine stockholders and vests based on the same market condition (see Note 3). The grant-date fair value of these awards, using a Monte Carlo valuation model, was $3.5 million. Based on the outcome of the market condition as of the September 30, 2022 and December 31, 2021 measurement dates, no shares were vested.

Outstanding rights to restricted stock awards and related activity for the nine months ended September 30, 2022 was as follows:

	Number of Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested balance – December 31, 2021	916,603	$ 10.00
Converted to shares of Common Stock upon vesting	(145,439)	—
Forfeited	(2,025)	9.84
Unvested balance – September 30, 2022	769,139	$ 9.84

As of September 30, 2022 and December 31, 2021, there was no unrecognized compensation cost related to unvested rights to restricted stock awards.

Note 14. Fair Value

Cash and cash equivalents are carried at fair value. Financial instruments, including accounts receivable, accounts payable, and accrued expenses are carried at cost, which approximates fair value given their short-term nature. Marketable securities, the Avenue Warrant, and the Contingent Earn-outs are carried at fair value. 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, which approximates fair value. The 2021 Avenue Loan, including the convertible notes payable and Conversion Feature, and the 2022 MD Loan are carried at amortized cost, which approximate fair value due to our credit risk and market interest rates.

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 September 30, 2022 is as follows:

	September 30, 2022			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 4,724	$ —	$ —	$ 4,724
Marketable securities				
Commercial paper	—	4,947	—	4,947
Corporate debt securities	—	4,019	—	4,019
Common stock warrant liability	—	—	18	18
Clene Nanomedicine contingent earn-out liability	—	—	11,438	11,438
Initial Stockholders contingent earn-out liability	—	—	1,468	1,468

The fair value hierarchy for financial instruments measured at fair value on a recurring basis as of December 31, 2021 is as follows:

	December 31, 2021			
(in thousands)	Level 1	Level 2	Level 3	Total
Notes payable	$ 736	$ —	$ —	$ 736
Common stock warrant liability	—	—	474	474
Clene Nanomedicine contingent earn-out liability	—	—	18,100	18,100
Initial Stockholders contingent earn-out liability	—	—	2,317	2,317

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 nine months ended September 30, 2022 were as follows:

(in thousands)	Common Stock Warrant Liability	Clene Nanomedicine Contingent Earn-out	Initial Stockholders Contingent Earn-out
Balance – December 31, 2021	$ 474	$ 18,100	$ 2,317
Change in fair value	(151)	(6,662)	(849)
Reclassification from liability to equity	(305)	—	—
Balance – September 30, 2022	$ 18	$ 11,438	$ 1,468

Changes in the fair value of our Level 3 financial instruments for the nine months ended September 30, 2021 were as follows:

(in thousands)	Common Stock Warrant Liability	Clene Nanomedicine Contingent Earn-out	Initial Stockholders Contingent Earn-out
Balance – December 31, 2020	$ —	$ 52,053	$ 5,906
Initial fair value of instrument	1,457	—	—
Change in fair value	(547)	(18,072)	(1,710)
Balance – September 30, 2021	$ 910	$ 33,981	$ 4,196

Valuation of Notes Payable and Convertible Notes Payable

As of September 30, 2022 and December 31, 2021, the carrying value of the 2019 MD Loan was $0.6 million and $0.6 million, respectively; and the carrying value of the 2019 Cecil Loan was $0.1 million and $0.1 million, respectively. In all periods presented, the loans were recorded at principal plus accrued interest in the condensed consolidated balance sheets.

As of September 30, 2022, the amortized cost of the 2021 Avenue Loan was $19.1 million, which included notes payable carried at $14.3 million; and convertible notes payable and embedded Conversion Feature, carried at $4.8 million. As of December 31, 2021, the amortized cost of the 2021 Avenue Loan was $18.3 million, which included notes payable carried at $13.7 million; and convertible notes payable and embedded Conversion Feature, carried at $4.6 million. The valuation of the Conversion Feature is discussed below. As of September 30, 2022, the amortized cost of the 2022 MD Loan was $0.7 million.

Valuation of Conversion Feature

The Conversion Feature of the convertible notes payable from the 2021 Avenue Loan is carried at amortized cost and did not meet the requirements for separate accounting as a derivative instrument. As of September 30, 2022 and December 31, 2021, the estimated fair value of the Conversion Feature was $0.3 million and $0.8 million, respectively, and was determined using a Black-Scholes option-pricing model. The unobservable inputs to the Black-Scholes option-pricing model were as follows:

	September 30, 2022	December 31, 2021
Expected stock price volatility	105.00%	105.00%
Risk-free interest rate	4.20%	0.70%
Expected dividend yield	0.00%	0.00%
Expected term	1.64 years	2.39 years

Valuation of the Common Stock Warrant Liability

The common stock warrant liability associated with the Avenue Warrant is comprised of the contingently issuable Tranche 2 warrant to purchase an estimated 184,133 shares of Common Stock, which was classified as a liability and recorded at fair value at issuance. The fair value and number of underlying shares will be remeasured at each reporting period.

The estimated fair value was determined using a Black-Scholes option-pricing model. The carrying amount of the liability may fluctuate significantly and actual amounts may be materially different from the liabilities' estimated value. The unobservable inputs to the Black-Scholes option-pricing model were as follows:

	September 30, 2022	December 31, 2021
Expected stock price volatility	115.00%	105.00%
Risk-free interest rate	4.20%	1.20%
Expected dividend yield	0.00%	0.00%
Expected term	3.47 years	3.89 – 4.39 years
Probability of drawing Tranche 2	5.00%	50.00%

As we did not complete a bona fide round of equity financing by March 31, 2022, the exercise price and underlying shares of 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 income (loss) and the Tranche 1 warrant liability was reclassified to additional paid-in-capital.

Valuation of the Contingent Earn-Out Liabilities

The Clene Nanomedicine and Initial Stockholders Contingent Earn-outs were recorded at fair value at the closing of the Reverse Recapitalization and are remeasured at each reporting period. As of September 30, 2022 and December 31, 2021, Clene Nanomedicine's common stockholders were entitled to receive up to 5,842,334 shares of Common Stock and the Initial Stockholders were entitled to receive up to 750,000 shares of Common Stock. As of December 31, 2021, we did not achieve Milestone 3 and the 2,503,851 Milestone 3 Contingent Earn-out shares were cancelled (see Note 3).

The estimated fair value of the Contingent Earn-outs is 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:

	September 30, 2022	December 31, 2021
Expected stock price volatility	115.00%	105.00%
Risk-free interest rate	4.20%	1.10%
Expected dividend yield	0.00%	0.00%
Expected term	3.25 years	4.00 years

Note 15. Common Stock

As of September 30, 2022 and December 31, 2021, our amended and restated certificate of incorporation 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.

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.

As of September 30, 2022 and December 31, 2021, our Common Stock issued and outstanding was 63,541,984 and 62,312,097 shares, respectively. As of September 30, 2022 and December 31, 2021, there was no preferred stock issued or outstanding.

Private Placements

Prior to the completion of the Reverse Recapitalization, we entered into subscription agreements with various investors (the "2020 PIPE") for the sale and issuance of 2,239,500 shares of Common Stock at a price of $10.00 per share, generating net proceeds of $22.2 million. In addition, investors in the 2020 PIPE also received warrants (the "PIPE Warrants") to purchase a number of shares equal to one-half (1/2) of the number of 2020 PIPE shares, totaling 1,119,750 shares of Common Stock, at $0.01 per share and subject to a 180-day holding period. Between July 1, 2021 and December 20, 2021, the PIPE Warrants were exercised in full for 1,119,750 shares of Common Stock. We received cash proceeds of $11,198.

In May 2021, we entered into subscription agreements with various investors (the "2021 PIPE") for the sale and issuance of 960,540 shares of Common Stock at a price of $9.63 per share, generating net proceeds of $9.3 million.

At-the-Market Facility

On April 14, 2022, we entered into an Equity Distribution Agreement (the "ATM Facility") with Canaccord Genuity LLC and Oppenheimer & Co. Inc., as placement agents (the "Placement Agents"). In accordance with the terms of the ATM Facility, 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 Agents. The issuance and sale of Common Stock, if any, by us under the ATM Facility 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 (the "SEC") on April 26, 2022, and our prospectus supplement relating to the offering.

Subject to terms of the ATM Facility, the Placement Agents are not required to sell any specific number or dollar amount of Common Stock but will act as our placement agents, using commercially reasonable efforts to sell, on our behalf, all of the Common Stock requested by us to be sold, consistent with the Placement Agents' normal trading and sales practices, on terms mutually agreed

between the Placement Agents and us. The Placement Agents will be entitled to compensation under the terms of the ATM Facility at a fixed commission rate of 3.0% of the gross proceeds from each issuance and sale of Common Stock, if any.

During the three and nine months ended September 30, 2022, we sold 40,000 shares of Common Stock under the ATM Facility and generated gross proceeds of $0.1 million. Commissions paid to the Placement Agents were insignificant.

Note 16. Net Loss Per Share

The computation of basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	**2022**	**2021**	**2022**	**2021**
Numerator:				
Net income (loss) attributable to common stockholders – Basic	$ (10,976)	$ 28,944	$ (28,864)	$ (14,163)
Less interest expense on potentially dilutive convertible notes payable	$ —	$ 196	$ —	$ —
Net income (loss) attributable to common stockholders – Diluted	$ (10,976)	$ 29,140	$ (28,864)	$ (14,163)
Denominator:				
Weighted average common shares outstanding – Basic	63,508,928	62,071,754	63,234,757	61,307,699
Weighted average effect of potentially dilutive securities:				
Stock options	—	5,791,023	—	—
Common stock warrants	—	1,485,049	—	—
Convertible notes payable	—	482,703	—	—
Restricted stock awards	—	208,105	—	—
Weighted average common shares outstanding – Diluted	63,508,928	70,038,634	63,234,757	61,307,699
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.17)	$ 0.47	$ (0.46)	$ (0.23)
Diluted	$ (0.17)	$ 0.42	$ (0.46)	$ (0.23)

The following shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2022 and 2021 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Convertible notes payable (see Note 9)	482,703	—	482,703	482,703
Common stock warrants (see Note 10)	4,477,045	2,547,934	4,477,045	4,594,545
Options to purchase common stock (see Note 13)	12,173,570	2,685,575	12,173,570	9,063,423
Unvested restricted stock awards (see Note 13)	769,139	1,100,050	769,139	1,245,489
Contingent earn-out shares (see Note 3)	6,592,334	9,096,185	6,592,334	9,096,185
Total	24,494,791	15,429,744	24,494,791	24,482,345

Note 17. Related Party Transactions

License and Supply Agreements

In August 2018, we entered into a license agreement and exclusive supply agreement (collectively, the "4Life Agreement") in conjunction with 4Life's investment in our Series C preferred stock and warrants. Pursuant to the 4Life Agreement, we granted 4Life an exclusive license to sell certain dietary supplements. The term of the exclusive license is five years from the commencement of product sales under the 4Life Agreement, which was in April 2021, with options to renew for additional five-year terms. We provide non-pharmaceutical product to 4Life for development, and 4Life pays royalties of 3% of incremental sales. 4Life is subject to an annual minimum sales requirement. If the minimum sales are unmet, 4Life may pay us an additional fee to maintain exclusivity or have the license converted to non-exclusive. Total revenue under the 4Life Agreement for the three and nine months ended September 30, 2022 and 2021 was as follows:

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Product revenue from related parties	$ 127	$ 51	$ 127	$ 376
Royalty revenue from related parties	44	47	100	124
Total revenue from related parties	$ 171	$ 98	$ 227	$ 500

Note 18. Geographic and Segment Information

Geographic Information

Long-lived assets, which were composed of property and equipment, net by location, as of September 30, 2022 and December 31, 2021, were as follows:

(in thousands)	September 30, 2022	December 31, 2021
United States	$ 9,753	$ 5,142
Australia	—	30
Total property and equipment, net	$ 9,753	$ 5,172

Segment Information

Our operating segment profit measure is segment loss from operations, which is calculated as revenue less cost of revenue, research and development, and general and administrative expenses. Profit and loss information by reportable segment for the three and nine months ended September 30, 2022 and 2021 was as follows:

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Drugs:				
Revenue from external customers	$ —	$ —	$ —	$ —
Depreciation expense	(222)	(223)	(681)	(700)
Stock compensation expense	2,098	2,425	6,484	9,945
Loss from operations	(10,073)	(10,546)	(37,012)	(35,632)
Supplements:				
Revenue from external customers	$ 174	$ 110	$ 239	$ 524
Depreciation expense	(11)	(12)	(34)	(34)
Stock compensation expense	—	—	—	—
Income (loss) from operations	268	96	276	(288)
Consolidated:				
Revenue from external customers	$ 174	$ 110	$ 239	$ 524
Depreciation expense	(233)	(235)	(715)	(734)
Stock compensation expense	2,098	2,425	6,484	9,945
Loss from operations	(9,805)	(10,450)	(36,736)	(35,920)

A reconciliation of the total of the reportable segments' loss from operations to consolidated net loss before income taxes for the three and nine months ended September 30, 2022 and 2021 was as follows:

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Segment loss from operations	$ (9,805)	$ (10,450)	$ (36,736)	$ (35,920)
Total other income (expense), net	(1,171)	39,325	7,872	21,544
Net income (loss) before income taxes	$ (10,976)	$ 28,875	$ (28,864)	$ (14,376)

Segment assets exclude corporate assets, such as cash, restricted cash, and corporate facilities. Total assets by reportable segment as of September 30, 2022 and December 31, 2021, were as follows:

(in thousands)	September 30, 2022	December 31, 2021
Total assets:		
Drugs	$ 19,106	$ 12,052
Supplements	331	337
Corporate	16,567	50,674
Consolidated	$ 36,004	$ 63,063

Additions to long-lived assets were through cash expenditure, accounts payable, and a lease incentive representing an allowance for facility alterations. For the nine months ended September 30, 2022 and 2021, total additions were as follows:

	Nine Months Ended September 30,	
(in thousands)	2022	2021
Drugs	$ 5,296	$ 661
Supplements	—	—
Corporate	—	—
Consolidated	$ 5,296	$ 661

Note 19. Subsequent Events

We have executed a non-binding Commitment Letter with DHCD to borrow $5.0 million, conditioned on the Company matching the $5.0 million loan with at least $5.0 million of new equity capital. We are targeting December 1, 2022 as the tentative closing date for the Loan Facility.

On October 3, 2022, we sold 318,769 shares of Common Stock under the ATM Facility and generated gross proceeds of $0.6 million. Commissions paid to the Placement Agents were insignificant. The issuance and sale of Common Stock under the ATM Facility 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.

On October 31, 2022, we entered into securities purchase agreement with certain of our existing stockholders, including stockholders affiliated with our directors, pursuant to which we agreed to issue and sell, in a registered direct offering (the “Offering”), 10,723,926 shares of Common Stock at a sale price of $1.01 per share. The Offering was made without a placement agent, underwriter, broker or dealer and the Company is not paying underwriting discounts or commissions. The aggregate gross proceeds, before expenses, were $10.8 million. The estimated total expenses of the Offering were approximately $20,000. 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.

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, or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. 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 now have multiple drug assets currently in development and/or clinical trials for applications in neurology, infectious disease, and oncology. Our development and clinical efforts are currently focused on addressing the high unmet medical needs in two areas: first, those related to central nervous system disorders including Amyotrophic Lateral Sclerosis ("ALS"), Multiple Sclerosis ("MS"), and Parkinson's Disease ("PD"); and second, those related to COVID-19, a highly infectious viral respiratory disease with serious and sometimes fatal co-morbidities.

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. We incurred a loss from operations of $9.8 million and $10.5 million for the three months ended September 30, 2022 and 2021, respectively; and $36.7 million and $35.9 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022 and December 31, 2021, we had an accumulated deficit of $192.2 million and $163.3 million, respectively.

We expect to continue investing in product development and we expect to incur additional losses in the future to fund our operations and conduct product research and development. We also 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.

Recent Developments of Our Clinical Programs

CNM-Au8®: We recently reported topline data from the Phase 2/3 Healey ALS Platform Trial, to establish the safety and efficacy of CNM-Au8® in patients with ALS. The primary endpoint of slope of change in ALS Functional Rating Scale Revised ("ALSFRS-R") scores adjusted for mortality was not significant (2% slowing, 95% CI: -20% to +19%) at 24 weeks. Secondary endpoints of Combined Assessment of Function and Survival ("CAFS") and Slow Vital Capacity ("SVC") were also not met at 24 weeks across the combined 30 mg and 60 mg CNM-Au8 doses.

The prespecified exploratory analyses of the secondary survival endpoint demonstrated a greater than 90% reduction in risk of death alone or in risk of death/permanently assisted ventilation at 24 weeks, when adjusted for baseline imbalances in risk (p=0.028 to p=0.075, unadjusted for multiple comparisons) with the CNM-Au8 30 mg dose. These survival results were statistically consistent for the 30 mg dose between the regimen only and full analysis sets, which included shared placebo from other regimens participating in the Healey ALS Platform Trial (Regimens A, B, and D). This survival signal is consistent with results previously reported by us in the Phase 2 RESCUE-ALS clinical trial with CNM-Au8.

The full analyses, including data on a subject level basis and exploratory efficacy parameters, are expected to be received from the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital (the "Healey Center") by the end of 2022 and we expect to announce the results in the first quarter of 2023. Additionally, we expect data on biomarkers of neurodegeneration in the first quarter of 2023. The open-label extension will continue to follow participants for an additional 52-week treatment period and we expect matured survival data in the second quarter of 2023. We are in discussions with the Healey Center to offer a broader Expanded Access Program of CNM-Au8 30 mg for eligible participants of closed regimens and others.

Based on these topline findings, we have selected the CNM-Au8 30 mg dose for continued development in ALS. The CNM-Au8 60 mg dose did not demonstrate a significant survival benefit. CNM-Au8 was well tolerated, and there were no drug-related serious adverse events or significant safety findings reported. We are presently discussing the design of an international Phase 3 study with expert ALS clinical advisors with the 30 mg dose, RESTORE-ALS.

We recently presented updated interim data from the RESCUE-ALS clinical trial long-term open-label extension at the American Association of Neuromuscular & Electrodiagnostic Medicine ("AANEM") Annual Meeting. The updated interim data demonstrated treatment with CNM-Au8 significantly improved long-term survival versus original placebo randomization, and compared to the European Network to Cure ALS ("ENCALS") predicted median survival.

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 mid-2023 after we receive the biomarker data and efficacy parameters that is forthcoming from the Healey ALS Platform Trial. We have paused our commercial expansion project at our Elkton, Maryland facility until we receive further clarity from the FDA on the path forward for CNM-Au8. The expansion of our North East, Maryland facility is on schedule; the North East, Maryland facility can meet current and future clinical development demand.

We recently reported positive topline data from our Phase 2 VISIONARY-MS clinical trial which evaluated the efficacy and safety of CNM-Au8 in stable relapsing remitting MS patients. The trial was stopped prematurely due to COVID-19 pandemic operational challenges, limiting enrollment to 73 out of the 150 planned participants. Due to the limited enrollment, the threshold for significance was pre-specified at p=0.10 prior to database lock. The primary analysis was conducted in a modified intent to treat ("mITT") population, which censored invalid data. The mITT population excluded data from a single site (n=9) with Low Contrast Letter Acuity ("LCLA") testing execution errors and the timed 25-foot walk data from one subject with a change in mobility assist device. The ITT results were directionally consistent with the mITT results, although the ITT results were not significant. The trial met the primary endpoint of change from baseline in LCLA at 48 weeks compared to placebo. The trial also met the secondary endpoints of mean standardized change from baseline in the modified MS Functional Composite ("mMSFC") and mMSFC average rank score.

The primary and secondary results from baseline to week 48 were:

- Primary outcome: LCLA letter change in the clinically affected eye (least squares ["LS"] mean difference, 3.13; 95% CI: -0.08 to 6.33, p = 0.056);
- Secondary outcomes:
  - mMSFC mean standardized change (LS mean difference, 0.28; 95% CI: 0.04 to 0.52, p = 0.0207);
  - mMSFC average rank score (LS mean difference, 13.38; 95% CI: 2.83 to 23.94, p = 0.0138); and

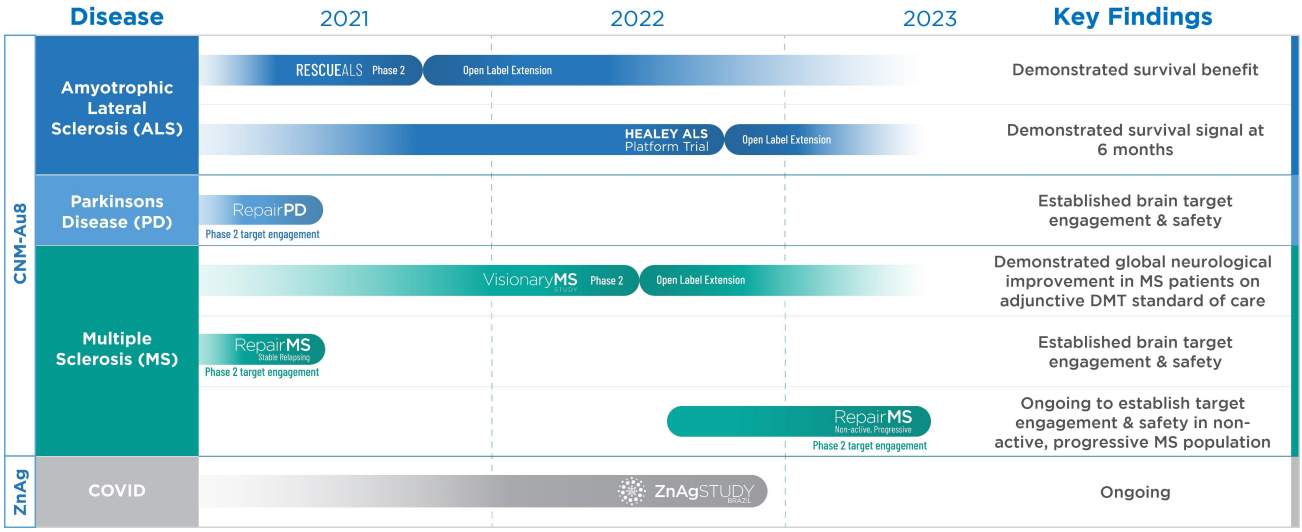
- time to first repeated clinical improvement to week 48 (45% vs. 29%, log-rank p=0.3991).

Consistent improvements favoring CNM-Au8 were observed across multiple paraclinical biomarkers, including multifocal visual evoked potentials amplitude and latency, optical coherence tomography, and MRI endpoints, including magnetization transfer ratio and diffusion tensor imaging metrics. Placebo treated patients, in contrast, generally worsened as expected across these measures during the 48-week period. These data provide independently assessed quantitative physiological evidence that supports the potential neuroprotective and remyelinating effects of CNM-Au8. CNM-Au8 was well-tolerated, and there were no significant safety findings reported. The open-label extension of VISIONARY-MS is ongoing.

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.

CNM-ZnAg: We have one Phase 2 clinical trial that recently concluded the blinded treatment period. The objective of this study is to investigate the efficacy and safety of CNM-ZnAg for the treatment of COVID-19. As pre-specified in the protocol, due to insufficient hospitalization events in the randomized study population, the primary and secondary endpoints were interchanged. The primary endpoint is now time to substantial alleviation of COVID-19 symptoms up to 28-days, over a continuous period greater than or equal to 48 hours. The key secondary endpoints include (i) time to complete alleviation of COVID-19 symptoms up to 28-days, over a continuous period greater than or equal to 48 hours; and (ii) the proportion of participants who are hospitalized, require hospitalization, or are deceased from baseline to day 28 (the original primary endpoint). Topline results are anticipated in the fourth quarter of 2022.

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 July 2022, the FDA accepted an NDA for tofersen, an investigational drug from Biogen Inc., for the treatment of superoxide dismutase 1 ALS. The NDA has been granted priority review with a Prescription Drug User Fee Act goal date of April 25, 2023. Additionally, in September 2022, the FDA approved AMX0035, now 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 September 2022, Biohaven Pharmaceutical Holding Company Ltd. announced its drug candidate, verdiperstat, did not demonstrate efficacy for the treatment of ALS in the Healey ALS Platform Trial.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the COVID-19 outbreak. The COVID-19 pandemic and government measures taken in response have

had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the COVID-19 pandemic and its effects on our business and operations remain uncertain. 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 have affected our ability to initiate and complete preclinical studies, caused manufacturing disruptions, and created delays at clinical trial site initiation and clinical trial enrollment, leading to the early conclusion of an ongoing clinical trial. The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds to support our operations. Moreover, the COVID-19 pandemic has significantly impacted economies worldwide and could result in adverse effects on our business and operations.

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 certain 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 and 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.

Reverse Recapitalization with Tottenham and Clene Nanomedicine

On December 30, 2020 (the "Closing Date"), Chelsea Worldwide Inc., our predecessor, consummated a business combination (the "Reverse Recapitalization") by and among Clene Nanomedicine, Inc. ("Clene Nanomedicine"), Tottenham Acquisition I Limited ("Tottenham"), Chelsea Worldwide Inc. ("PubCo"), a Delaware corporation and wholly-owned subsidiary of Tottenham, Creative Worldwide Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of PubCo, and Fortis Advisors LLC, a Delaware limited liability company as the representative of our stockholders. Prior to the Reverse Recapitalization, Tottenham was incorporated in the British Virgin Islands as a blank check company for the purpose of entering into a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization, or other similar business combination with one or more businesses or entities. Prior to the Reverse Recapitalization, there was not a public market for the shares of Clene Nanomedicine common stock.

The Reverse Recapitalization was effected in two steps: (i) Tottenham was reincorporated to the state of Delaware by merging with and into PubCo; and (ii) Merger Sub was merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine becoming a wholly-owned subsidiary of PubCo. On the Closing Date, PubCo changed its name from Chelsea Worldwide Inc. 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."

Earn-Out Shares

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. The Contingent Earn-outs have been classified as liabilities in the condensed consolidated balance sheets and were initially measured at fair value on the date of the Reverse Recapitalization and are subsequently remeasured to fair value at each reporting date. The change in fair value of the Contingent Earn-outs has been recorded in the condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2022 and 2021.

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, with two clinical-stage drug candidates currently being investigated.

Historically, substantially all of our research and development expenses relate to CNM-Au8, our lead 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 new drug programs commenced. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to per patient clinical trial site fees for larger clinical trials, the costs of opening and monitoring clinical sites, CRO activity, and manufacturing expenses. We anticipate that our research and development expenses will increase significantly due to the increase in clinical trial expenses incurred to develop our drug candidates.

Research and development costs are charged to operations as incurred. Research and development costs include payroll and personnel expenses, including salaries and related benefits and stock-based compensation expense for employees engaged in research and development functions; clinical trial supplies and materials to support our clinical trials; payments to CROs, principal investigators, and clinical trial sites; costs associated with preclinical activities; consulting costs; and allocated overhead, including rent, equipment, utilities, depreciation, insurance, and facilities maintenance costs. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities initially as an asset and then as expenses when the goods have been received or when the service has been performed rather than when the payment is made.

Our clinical trial accrual process seeks to account for expenses resulting from obligations under contracts with CROs, consultants, and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract 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 trial expenses in the condensed consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments will be recorded as a prepaid asset, which will be expensed over the period of time the contracted services are performed.

General and Administrative Expense

General and administrative expenses consist primarily of payroll and personnel expenses, including salaries and related benefits and stock-based compensation expense; professional 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; utilities and facility expenses; travel expenses; rental fees; consulting fees; and other administrative expenses.

Our expectation for our general and administrative expenses in future periods is contingent on the outcome of our end of Phase 2 meeting with the FDA, which is expected in mid-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.

If we are able to file an NDA with the FDA based on our accumulation of clinical evidence, we would expect our general and administrative expenses to 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 not able to file an NDA based on our accumulation of clinical evidence, we would need to continue investing in clinical research activities and we would expect our general and administrative expenses to decrease in future periods as we decrease commercial expansion projects, including at our Elkton, Maryland facility, and as we implement cost-saving initiatives, including potentially delaying or reducing launch plus commercialization efforts, 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 extinguishment of notes payable, (v) gains and losses on termination of leases, and (vi) the Australia research and development credit.

We also received grants issued by non-government entities which require us to comply with conditions attached to the grants. Income from grants is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants were provided have been met. We receive tax incentives from the Australian government in the form of cash subsidies for research and development activities related to clinical trial activities conducted by our Australian subsidiary, which are recognized as other income upon compliance with certain conditions.

Results of Operations

Our results of operations for the three and nine months ended September 30, 2022 and 2021 were as follows:

(in thousands)	Three Months Ended September 30, 2022	2021	Change Dollars	%	Nine Months Ended September 30, 2022	2021	Change Dollars	%
Product revenue	$ 130	$ 63	$ 67	106%	$ 139	$ 400	$ (261)	(65)%
Royalty revenue	44	47	(3)	(6)%	100	124	(24)	(19)%
Total revenue	174	110	64	58%	239	524	(285)	(54)%
Operating expenses:								
Cost of revenue	19	14	5	36%	19	812	(793)	(98)%
Research and development	6,403	6,146	257	4%	24,149	18,893	5,256	28%
General and administrative	3,557	4,400	(843)	(19)%	12,807	16,739	(3,932)	(23)%
Total operating expenses	9,979	10,560	(581)	(6)%	36,975	36,444	531	1%
Loss from operations	(9,805)	(10,450)	645	6%	(36,736)	(35,920)	(816)	(2)%
Total other income (expense), net	(1,171)	39,325	(40,496)	(103)%	7,872	21,544	(13,672)	(63)%
Net income (loss) before income taxes	(10,976)	28,875	(39,851)	(138)%	(28,864)	(14,376)	(14,488)	(101)%
Income tax benefit	—	69	(69)	(100)%	—	213	(213)	(100)%
Net income (loss)	$ (10,976)	$ 28,944	$ (39,920)	(138)%	$ (28,864)	$ (14,163)	$ (14,701)	(104)%

Revenue

Product revenue totaled $0.1 million and $0.1 million for the three months ended September 30, 2022 and 2021, respectively; and $0.1 million and $0.4 million for the nine months ended September 30, 2022 and 2021, 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 and nine months ended September 30, 2022, 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 $44,000 and $47,000 for the three months ended September 30, 2022 and 2021, respectively; and $0.1 million and $0.1 million for the nine months ended September 30, 2022 and 2021, respectively, under an exclusive and royalty-bearing license agreement with 4Life relating to the sale of Gold Factor. For more details on the supply and license agreements, see Note 17 to our condensed consolidated financial statements.

Cost of Revenue

Cost of revenue totaled $19,000 and $14,000 for the three months ended September 30, 2022 and 2021, respectively; and $19,000 and $0.8 million for the nine months ended September 30, 2022 and 2021, 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 and nine months ended September 30, 2022 and 2021 was as follows:

(in thousands)	Three Months Ended September 30, 2022	2021	Change Dollars	%	Nine Months Ended September 30, 2022	2021	Change Dollars	%
CNM-Au8	$ 2,083	$ 2,402	$ (319)	(13)%	$ 7,916	$ 6,908	$ 1,008	15%
CNM-ZnAg	638	153	485	317%	2,531	670	1,861	278%
Unallocated	711	794	(83)	(10)%	3,894	2,081	1,813	87%
Personnel	2,120	1,939	181	9%	7,380	5,373	2,007	37%
Stock-based compensation	851	858	(7)	(1)%	2,428	3,861	(1,433)	(37)%
Total research and development	$ 6,403	$ 6,146	$ 257	4%	$ 24,149	$ 18,893	$ 5,256	28%

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, for the three months ended September 30, 2022, primarily due to a decrease in expenses in the REPAIR-PD, RESCUE-ALS, 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;

(ii) an increase in expenses related to our lead drug candidate, CNM-Au8, for the nine months ended September 30, 2022 primarily due to the progression of the clinical development process, including the timing of calendar payments for our participation in the Healey ALS Platform Trial and an increase in expenses in the REPAIR-MS clinical trial due to initiation of a second dosing cohort, which was partially offset by a decrease in expenses in the REPAIR-PD, RESCUE-ALS, 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;

(iii) an increase in expenses related to CNM-ZnAg, primarily due to the progression of the clinical development process, including full enrollment in the clinical trial for treatment of COVID-19;

(iv) an increase in unallocated expenses for the nine months ended September 30, 2022, primarily due to increased rent and utility expenses related to our newly-leased facility in Elkton, Maryland and our expanded facility in North East, Maryland; increased research, manufacturing, and materials expenses; and decreased grant revenue; partially offset by decreased depreciation expense;

(v) an increase in personnel expenses, primarily due to our increased headcount; and

(vi) a decrease in stock-based compensation expense, primarily due to a decrease in stock-based compensation expense from restricted stock awards, partially offset by an increase in stock-based compensation expense from stock options.

General and Administrative Expense

General and administrative expense for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in thousands)	2022	2021	Dollars	%	2022	2021	Dollars	%
Directors' and officers' insurance	$ 849	$ 929	$ (80)	(9)%	$ 2,547	$ 2,832	$ (285)	(10)%
Legal	87	389	(302)	(78)%	414	1,034	(620)	(60)%
Finance and accounting	217	227	(10)	(4)%	901	2,568	(1,667)	(65)%
Public and investor relations	124	264	(140)	(53)%	593	1,141	(548)	(48)%
Personnel	706	787	(81)	(10)%	3,147	2,416	731	30%
Stock-based compensation	1,247	1,567	(320)	(20)%	4,056	6,084	(2,028)	(33)%
Other	327	237	90	38%	1,149	664	485	73%
Total general and administrative	$ 3,557	$ 4,400	$ (843)	(19)%	$ 12,807	$ 16,739	$ (3,932)	(23)%

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 the Reverse Recapitalization and subsequent registration statement filings with the SEC, decreased patent and trademark expenses, decreased fees related to financing and fundraising, and a decrease in other general corporate legal fees;

(iii) a decrease in finance and accounting fees after completing the Reverse Recapitalization and subsequent filings with the SEC, including decreased fees from consultants and other financial vendors; decreased fees for various institutions, investment bankers, advisors, and auditors; partially offset by an increase in tax fees;

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

(v) an increase in personnel expenses for the nine months ended September 30, 2022, primarily due to our increased headcount in the first half of 2022;

(vi) a decrease in stock-based compensation expense, primarily due to a decrease in stock-based compensation expense from restricted stock awards, partially offset by an increase in stock-based compensation expense from stock options; and

(vii) an increase in other expenses, primarily due to an increase in expenses related to business development, travel, information technology, supplies and equipment, corporate and liability insurance, and depreciation; and increased rent and utility expenses related to our newly-leased facility in Elkton, Maryland and our expanded facility in North East, Maryland; partially offset by a decrease in office and professional expenses.

Total Other Income (Expense), Net

Total other income (expense), net, for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in thousands)	2022	2021	Dollars	%	2022	2021	Dollars	%
Interest expense	$ (857)	$ 80	$ (937)	(1,171)%	$ (2,390)	$ (497)	$ (1,893)	(381)%
Gain on extinguishment of notes payable	—	—	—	0%	—	647	(647)	(100)%
Gain on termination of lease	—	—	—	0%	420	—	420	100%
Change in fair value of common stock warrant liability	149	414	(265)	(64)%	151	547	(396)	(72)%
Change in fair value of Clene Nanomedicine contingent earn-out liability	(1,591)	35,042	(36,633)	(105)%	6,662	18,072	(11,410)	(63)%
Change in fair value of Initial Stockholders contingent earn-out liability	(205)	3,439	(3,644)	(106)%	849	1,710	(861)	(50)%
Australia research and development credit	1,346	364	982	270%	2,001	1,078	923	86%
Other income (expense), net	(13)	(14)	1	7%	179	(13)	192	1,477%
Total other income (expense), net	$ (1,171)	$ 39,325	$ (40,496)	(103)%	$ 7,872	$ 21,544	$ (13,672)	(63)%

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

(i) an increase in interest expense primarily due to increased interest expense and amortization of debt discount and debt issuance costs on notes payable, partially offset by a decrease in the carrying value of the 2019 MD Loan and 2019 Cecil Loan due to changes in the price of our Common Stock on Nasdaq;

(ii) gain on extinguishment of debt due to forgiveness of a Paycheck Protection Program loan (the "PPP Loan") by the United States ("U.S.") Small Business Administration during the nine months ended September 30, 2021;

(iii) gain on termination of lease due to the termination of an operating lease for office space for the nine months ended September 30, 2022;

(iv) a gain from a decrease in fair value of the Clene Nanomedicine Contingent Earn-out liability and Initial Stockholders Contingent Earn-out liability for the nine months ended September 30, 2022 and 2021 and the three months ended September 30, 2021; and a loss from an increase in the fair value of the liabilities for the three months ended September 30, 2022. The changes in fair value were due to changes in the price of our Common Stock on Nasdaq and updates in the valuation model assumptions (see "Critical Accounting Policies and Estimates");

(v) income due to the Australia research and development credit. We recognized Australia research and development credit in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage; and

(vi) other income (expense), net, primarily due to interest income on cash, cash equivalents, and marketable securities and realized gains and losses on foreign currency transactions.

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% for the three and nine months ended September 30, 2022 and 2021. We are also subject to state income tax in Utah and Maryland, at a rate of 4.85% and 8.25%, respectively, for the three and nine months ended September 30, 2022 and 2021. As of September 30, 2022 and December 31, 2021, 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 on March 5, 2018 and is subject to corporate income tax at a rate of 25% for the three and nine months ended September 30, 2022 and 2021, respectively. Clene Australia income tax benefit totaled $0 and $0.1 million for the three months ended September 30, 2022 and 2021, respectively; and $0 and $0.2 million for the nine months ended September 30, 2022 and 2021, respectively. We recorded other income of $1.3 million and $0.4 million for the three months ended September 30, 2022 and 2021, respectively; and $2.0 million and $1.1 million for the nine months ended September 30, 2022 and 2021, respectively, for research and development credits pertaining to Clene Australia for the 2022 and 2021 tax years, respectively.

Netherlands

Our wholly-owned subsidiary, Clene Netherlands B.V., was established in the Netherlands on April 21, 2021 and is subject to corporate income tax at a rate of 15% up to €395,000 of taxable income and 25.8% for taxable income in excess of €395,000. Clene Netherlands B.V. had no taxable income or provision for income taxes for the three and nine months ended September 30, 2022 and 2021.

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 product research and development. 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 $130.2 million from equity financing, including sales of common stock, preferred stock, warrants to purchase common stock, and our ATM offering program;
- gross proceeds of $32.3 million from borrowings under convertible promissory notes;
- gross proceeds of $21.9 million from borrowings under notes payable;
- gross proceeds of $9.4 million from the Reverse Recapitalization;
- gross proceeds of $5.4 million from refundable research and development tax credits;
- gross proceeds of $2.3 million from grants from various organizations; and
- gross proceeds of $0.9 million from stock option 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 $9.8 million and $10.5 million for the three months ended September 30, 2022 and 2021, respectively; and $36.7 million and $35.9 million for the nine months ended September 30, 2022 and 2021, respectively. Our accumulated deficit was $192.2 million and $163.3 million as of September 30, 2022 and December 31, 2021, respectively. Our cash, cash equivalents, and marketable securities totaled $16.2 million and $50.3 million as of September 30, 2022 and December 31, 2021, respectively, and net cash used in operating activities was $31.3 million and $25.0 million for the nine months ended September 30, 2022 and 2021, 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.

Our management performs strategic reviews of our operating plans and budgets, considering the status of our product development programs, human capital, capital needs and resources, and current capital market conditions. Based on these reviews, our Board of Directors and management make adjustments to our operating plans and budgets to allocate our projected cash expenditures. Notwithstanding these ongoing adjustments, we project 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, and we must obtain additional financing. Additionally, pursuant to our term loan with Avenue Venture Opportunities Fund, L.P. ("Avenue"), we must maintain unrestricted cash and cash equivalents of at least $5.0 million to avoid acceleration of the full balance of the loan. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

To mitigate our funding needs, we intend to implement plans to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as potentially utilizing additional funds available under our term loan with Avenue, subject to certain contingent conditions (see Note 9), as well as our existing at-the-market facility. 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. In October 2022, we announced an equity offering which provided net cash proceeds of $10.8 million. We are also in the process of implementing cost-saving initiatives, including potentially delaying or 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 $1.0 million of payments under finance and operating lease obligations, respectively; payment of principal and interest on notes payable totaling $5.9 million; and commitments under various agreements for capital expenditures totaling $1.7 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 $0.1 million and $7.8 million of payments under finance and operating lease obligations, respectively; and interest and principal repayment of notes payable of $20.3 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 nine months ended September 30, 2022 and 2021 were as follows:

	Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (31,295)	$ (25,018)
Net cash used in investing activities	(12,446)	(661)
Net cash provided by financing activities	875	27,130
Effect of foreign exchange rate changes on cash	(155)	(116)
Net increase (decrease) in cash	$ (43,021)	$ 1,335

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 $31.3 million for the nine months ended September 30, 2022, which resulted from a net loss of $28.9 million, adjusted for non-cash items totaling $0.1 million and a net change in operating assets and liabilities of $2.6 million. Significant non-cash items included (i) depreciation expense of $0.7 million relating to laboratory and office equipment and leasehold improvements; (ii) non-cash lease expense of $0.3 million; (iii) stock-based compensation expense of $6.5 million; (iv) gain on termination of lease of $0.4 million; (v) accretion of debt discount of $0.7 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 $6.7 million and $0.8 million, respectively, and the change in fair value of common stock warrant liability of $0.2 million. 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 receivable of $0.1 million and an increase in accounts payable of $0.2 million due to the timing of vendor invoicing and payments; (b) an increase in prepaid expenses and other current assets of $0.9 million due to the timing of vendor invoicing and payments, the timing of receipt of metals to be used in research and development, and an increase in Australia research and development credit receivable; (c) a decrease in accrued liabilities of $1.5 million primarily due to decreased accrued compensation and benefits; and (d) a decrease in operating lease obligations of $0.4 million.

Net cash used in operating activities was $25.0 million for the nine months ended September 30, 2021, which resulted from a net loss of $14.2 million, adjusted for non-cash items totaling $10.4 million and a net change in operating assets and liabilities of $0.5 million. Non-cash items primarily consisted of the following: (i) depreciation expense of $0.7 million, (ii) stock-based compensation expense of $9.9 million, (iii) change in fair value of Clene Nanomedicine Contingent Earn-out of $18.1 million, (iv) change in fair value of Initial Stockholders Contingent Earn-out of $1.7 million, (iv) gain on extinguishment of debt of $0.6 million and increase in interest accrued on notes payable and accretion of debt discount of $0.1 million. The net change in operating assets and liabilities was primarily attributable to the following: (a) a decrease in inventory of $0.2 million, (b) an increase in accounts receivable of $48,000, (c) an increase in prepaid expenses and other current assets of $1.2 million due to the increase in Australia research and development credit receivable, metal to be used in research and development, and directors and officers insurance; partially offset by a decrease in CRO prepayments, (d) an increase in accounts payable of $0.4 million, (e) a decrease in operating lease obligations of $0.1 million, (f) an increase in accrued liabilities of $0.5 million due to the timing of vendor invoicing and payments, and (g) a decrease in deferred income tax of $0.2 million.

Investing Activities

Net cash used in investing activities was $12.4 million for the nine months ended September 30, 2022, which consisted of (i) purchases of marketable securities of $24.6 million and (ii) purchases of property and equipment of $3.5 million, offset primarily by (iii) proceeds from maturity of marketable securities of $8.0 million and (iv) proceeds from sale of marketable securities of $7.6 million. Net cash used in investing activities was $0.7 million for the nine months ended September 30, 2021, which consisted of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $0.9 million for the nine months ended September 30, 2022, which primarily consisted of (i) proceeds from exercise of stock options of $0.3 million, (ii) at-the-market offering proceeds of $0.1 million net of $4,000 placement agent commissions, and (iii) proceeds from the issuance of notes payable of $0.7 million, offset primarily by (iv) payments of finance lease obligations of $0.1 million, (v) payment of debt issuance costs of $30,000, and (vi) payment of deferred offering costs of $0.1 million. Net cash provided by financing activities was $27.1 million for the nine months ended September 30, 2021, which primarily consisted of (i) proceeds from exercise of stock options of $0.4 million, (ii) proceeds from the issuance of notes payable of $20.0 million offset by payments of debt issuance costs of $0.5 million, and (iii) proceeds from the May 2021 private placement of

common stock of $9.3 million, offset primarily by (iv) payments of finance lease obligations of $0.1 million and (v) payments of deferred offering costs of $1.9 million.

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. The agreement provides for a term loan of $0.5 million bearing simple interest at an annual rate of 8.00%. We are subject to affirmative and negative covenants until maturity, including providing information about the Company and our operations; 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. There are no financial covenants associated with the 2019 MD Loan. We are not in violation of any covenants. The 2019 MD Loan established "Phantom Shares" at issuance 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 the balance of principal plus accrued interest or the value of the Phantom Shares. The value of the Phantom Shares is based on the closing price of our Common Stock on Nasdaq at the end of each reporting period. As of September 30, 2022 and December 31, 2021, the note was recorded at principal plus accrued interest in the condensed consolidated balance sheets.

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 the production of pharmaceutical drugs. As of September 30, 2022, we had drawn $0.7 million under the term loan, with the remainder available upon our submission of disbursement requests to purchase the Assets. The 2022 MD Loan matures on July 1, 2027 (the "Maturity Date"). The first twelve payments, commencing on July 1, 2022, are deferred. Immediately thereafter, there shall be eighteen monthly installments of interest-only based on the actual amount advanced under the loan, each up to a maximum amount of $15,000; followed by thirty monthly installments of principal and interest, each in the amount of $33,306, which is due and payable even if the entire loan has not been advanced prior to the date such monthly payment is due and payable, with a balloon payment of all accrued and unpaid interest and principal due on the Maturity Date. We recorded $31,000 of debt issuance costs that are being amortized over the contractual term using the effective interest method. Pursuant to the 2022 MD Loan, DHCD was granted a continuing security interest in the Assets as collateral. Under a priority of liens agreement by and between DHCD and Avenue Venture Opportunities Fund, L.P. ("Avenue"), an existing secured creditor of the Company, DHCD's continuing security interest in the Assets shall be a first priority lien.

Advance Cecil Inc. 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. The agreement provides for a term loan of $0.1 million bearing simple interest at an annual rate of 8.00%. We are subject to affirmative covenants until maturity, including providing information about the Company and our operations. There are no financial covenants associated with the 2019 Cecil Loan. We are not in violation of any covenants. The 2019 Cecil Loan established "Phantom Shares" at issuance 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 the balance of principal plus accrued interest or the value of the Phantom Shares. The value of the Phantom Shares is based on the closing price of our Common Stock on Nasdaq at the end of each reporting period. As of September 30, 2022 and December 31, 2021, the note was recorded at principal plus accrued interest in the condensed consolidated balance sheets.

Avenue Loan

In May 2021, we entered into a loan agreement (the "2021 Avenue Loan") with Avenue. The agreement provides for a 42-month term loan of up to $30.0 million. The first tranche is $20.0 million ("Tranche 1"), of which $15.0 million was funded at close and $5.0 million was funded in September 2021. We incurred issuance costs of $0.6 million of which $46,951 was expensed immediately. The remaining unfunded tranche of $10.0 million ("Tranche 2") is available until December 31, 2022. Funding of Tranche 2 is subject to (a) our receipt of $5.0 million financing through the state of Maryland; (b) our achievement of a statistically significant result in certain clinical trials ("Performance Milestone 1"); (c) our receipt of net proceeds of at least $30.0 million from the sale and issuance of our equity securities between May 2, 2021 and December 31, 2022; and (d) mutual agreement of us and Avenue. The 2021 Avenue Loan bears interest at a variable rate equal to the sum of (i) the greater of (a) the prime rate or (b) 3.25%, plus (ii) 6.60%. As of September 30, 2022 and December 31, 2021, the interest rate was 12.85% and 9.85%, respectively. Payments are interest-only for the first 12 months and have been extended an additional 12 months (the "First Interest-only Period Extension") based on our achievement of Performance Milestone 1. Payments may be extended up to 36 months if we (i) achieve the First Interest-only Period Extension and (b) draw from Tranche 2. The loan principal will amortize equally from the end of the interest period to the expiration of the 42-month term on December 1, 2024. On the maturity date, an additional payment equal to 4.25% of the funded loans, currently equal to $0.9 million (the "Final Payment"), is due in addition to the remaining unpaid principal and accrued interest. The Final Payment was recorded as a debt premium and is being amortized over the contractual term using the effective interest method. The Final Payment is related to the loan

host and is not bifurcated pursuant to Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging* ("ASC 815"). We are subject to affirmative and negative covenants until maturity in the absence of prepayments, including providing information about the Company and our operations; limitation on our ability to retire, repurchase, or redeem our Common Stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. Also pursuant to the 2021 Avenue Loan, we are required to maintain unrestricted cash and cash equivalents of at least $5.0 million, provided that upon our (i) achievement of Performance Milestone 1, and (ii) receiving of net proceeds of at least $30.0 million from the sale and issuance of our equity securities, we shall no longer be subject to financial covenants. We are not in violation of any covenants. Avenue also has the ability to make all obligations under the 2021 Avenue Loan immediately due and payable upon occurrence of certain events of default or material adverse effects, as outlined in the loan agreement. 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.

Pursuant to the agreement, we granted Avenue a warrant to purchase 115,851 shares of Common Stock (the "Avenue Warrant") at an exercise price of $8.63 per share. Upon the funding of Tranche 2, the Avenue Warrant shall be adjusted to include an additional estimated 184,133 shares of Common Stock, which is equal to 5% of the principal amount of Tranche 2, divided by the five (5)-day VWAP per share as of the end of trading on the last trading day before the issuance of Tranche 2. We accounted for the Tranche 2 contingently-issuable warrant at inception of the 2021 Avenue Loan in accordance with ASC 815 and the fair value and issuable shares are remeasured at each reporting period.

Avenue has the right, in its discretion, but not the obligation, at any time between May 21, 2022 through May 21, 2024, while the loan is outstanding, to convert up to $5.0 million of principal into Common Stock (the "Conversion Feature") at a price per share equal to 120% of the Avenue Warrant exercise price. The Conversion Feature is subject to certain minimum price and volume conditions of our Common Stock on Nasdaq. The Conversion Feature did not meet the requirements for separate accounting and is not accounted for as a derivative instrument. The number of shares of Common Stock contingently issuable upon conversion is 482,703 shares. We classified $5.0 million of the 2021 Avenue Loan as convertible notes payable as of September 30, 2022 and December 31, 2021, with unamortized debt discount and issuance costs of $0.2 million and $0.4 million, respectively.

At-the-Market Facility

On April 14, 2022, we entered into an Equity Distribution Agreement (the "ATM Facility") with Canaccord Genuity LLC and Oppenheimer & Co. Inc., as placement agents (the "Placement Agents"). In accordance with the terms of the ATM Facility, 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 Agents. The issuance and sale of Common Stock, if any, by us under the ATM Facility 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 Facility, the Placement Agents are not required to sell any specific number or dollar amount of Common Stock but will act as our placement agents, using commercially reasonable efforts to sell, on our behalf, all of the Common Stock requested by us to be sold, consistent with the Placement Agents' normal trading and sales practices, on terms mutually agreed between the Placement Agents and us. The Placement Agents will be entitled to compensation under the terms of the ATM Facility at a fixed commission rate of 3.0% of the gross proceeds from each issuance and sale of Common Stock, if any.

During the three and nine months ended September 30, 2022, we sold 40,000 shares of Common Stock under the ATM Facility and generated gross proceeds of $0.1 million. Commissions paid to the Placement Agents were insignificant.

Critical Accounting Policies and 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. See Note 2 to our condensed consolidated financial statements for a description of other significant accounting policies.

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 income (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 September 30, 2022 and December 31, 2021, the unobservable inputs were as follows:

	September 30, 2022	December 31, 2021
Expected stock price volatility	115.00%	105.00%
Risk-free interest rate	4.20%	1.10%
Expected dividend yield	0.00%	0.00%
Expected term	3.25 years	4.00 years

The change in fair value of the Clene Nanomedicine Contingent Earn-out resulted in a loss of $1.6 million and gain of $35.0 million for the three months ended September 30, 2022 and 2021, respectively; and gains of $6.7 million and $18.1 million for the nine months ended September 30, 2022 and 2021, respectively. The change in fair value of the Initial Stockholders Contingent Earn-out resulted in a loss of $0.2 million and gain of $3.4 million for the three months ended September 30, 2022 and 2021, respectively; and gains of $0.8 million and $1.7 million for the nine months ended September 30, 2022 and 2021, respectively.

Convertible Notes

Pursuant to the 2021 Avenue Loan, $5.0 million of the outstanding principal is subject to the Conversion Feature. In accordance with Accounting Standards Update ("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 bifurcate the Conversion Feature from the host contract. Consequently, we account for the convertible note as a single liability measured at its amortized cost. As of September 30, 2022 and December 31, 2021, the convertible note was carried at $4.8 million and $4.6 million, respectively.

Common Stock Warrant Liability

Pursuant to the 2021 Avenue Loan, we issued the Avenue Warrant. In accordance with ASC 815, we recognized both the issued Tranche 1 warrant and the Tranche 2 warrant issuable pursuant to the potential draw of Tranche 2 as liabilities measured at fair value. As we did not complete a bona fide round of equity financing by March 31, 2022, the exercise price and underlying shares of 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 income (loss) and the Tranche 1 warrant liability was reclassified to additional paid-in-capital. We remeasure the Tranche 2 warrant liability 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 income (loss).

We estimate the fair value using a Black-Scholes option-pricing model, with a probability weight related to the potential draw of Tranche 2, which requires significant judgment. The unobservable inputs include the expected stock price volatility, risk-free interest rate, expected term, and the probability of drawing Tranche 2. As of September 30, 2022 and December 31, 2021, the unobservable inputs were as follows:

	September 30, 2022	December 31, 2021
Expected stock price volatility	115.00%	105.00%
Risk-free interest rate	4.20%	1.20%
Expected dividend yield	0.00%	0.00%
Expected term	3.47 years	3.89 – 4.39 years
Probability of drawing Tranche 2	5.00%	50.00%

We recorded a change in fair value of the common stock warrant liability of $0.1 million and $0.4 million for the three months ended September 30, 2022 and 2021, respectively; and $0.2 million and $0.5 million for the nine months ended September 30, 2022 and 2021, 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 nine months ended September 30, 2022 and 2021, the unobservable inputs were as follows:

	Nine Months Ended September 30,	
	2022	2021
Expected stock price volatility	89.57% – 98.13%	84.80% – 87.40%
Risk-free interest rate	1.65% – 3.00%	0.59% – 0.94%
Expected dividend yield	0.00%	0.00%
Expected term of options	5.00 – 6.98 years	6.00 years

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 nine months ended September 30, 2022 and 2021.

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 September 30, 2022, 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 September 30, 2022, 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, 2021 and 2020, 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 weakness. During 2021, 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 Vice President, Finance and Controller;
- we have engaged external consultants to assist with the evaluation of complex accounting and financial reporting related areas and to assist with the documentation around accounting and financial reporting policies and procedures;
- we engaged external consultants to assist in the design, implementation, and documentation of internal controls that address the relevant risks and provide for appropriate evidence of performance of the internal control; and
- we implemented a new Enterprise Resource Planning ("ERP") system that will significantly enhance the information technology general controls environment.

Our remediation activities are continuing during 2022. 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;
- 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, and to assist us with documenting and assessing our accounting policies and procedures; and

- implemented a new ERP to enhance the accuracy of our financial records, enable the enforcement of systematic segregation of duties, and improve our information technology general controls environment.

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 weakness 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 September 30, 2022, 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 2021 Annual Report on Form 10-K which was filed with the SEC on March 11, 2022. There have been no material changes to the risk factors since previously disclosed in the 2021 Annual Report on Form 10-K. Any one or more of these factors could, directly or indirectly, cause our actual financial condition and results of operations to vary materially from past, or from anticipated future, financial condition and results of operations. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price.

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

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds

None.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description
3.1	Third Amended and Restated Certificate of Incorporation of Clene Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Registrant on July 16, 2021).
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	Amended and Restated Promissory Note, dated August 5, 2022, by Clene Nanomedicine, Inc. to the Department of Housing and Community Development, a principal department of the State of Maryland (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q filed by the Registrant on August 15, 2022).
10.2#	Second Amendment to Loan and Security Agreement, dated August 9, 2022, by and between Clene Inc., Clene Nanomedicine, Inc. and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q filed by the Registrant on August 15, 2022).
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: November 7, 2022

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

Dated: November 7, 2022

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: November 7, 2022

/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: November 7, 2022

/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 September 30, 2022, 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: November 7, 2022

/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 September 30, 2022, 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: November 7, 2022

/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.