PROSPECTUS SUPPLEMENT NO. 5
(To Prospectus Dated April 19, 2021)
Registration No. 333-253173

Filed Pursuant to Rule 424(b)(3)

PROSPECTUS SUPPLEMENT NO. 1
(To Prospectus Dated August 2, 2021)
Registration No. 333-258098

Up to 29,894,305 Shares of Common Stock

This Prospectus Supplement (the "**Supplement**") is being filed by Clene Inc. (the "**Company**") to update and supplement the Company's (i) prospectus, dated April 19, 2021 ("**Prospectus #1**"), as supplemented from time to time, which forms a part of the Company's Registration Statement on Form S-1 (Registration No. 333-253173) relating to the resale of up to 27,793,034 shares of the Company's common stock ("**Common Stock**") by the selling shareholders identified in the prospectus; and (ii) prospectus, dated August 2, 2021 ("**Prospectus #2**" and together with Prospectus #1, the "**Prospectuses**"), which forms a part of the Company's Registration Statement on Form S-1 (Registration No. 333-258098) relating to the resale of up to 2,101,271 shares of Common Stock by the selling shareholders identified in the prospectus. This Supplement should be read in conjunction with the Prospectuses, and this Supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectuses, including any amendments or supplements thereto.

If there is any inconsistency between the information in the Prospectuses and this Supplement, you should rely on the information in this Supplement.

This Supplement is being filed to update the information in the Prospectuses with the information contained in the Company's (i) Quarterly Report on Form 10-Q (the "**Quarterly Report**") filed with the U.S. Securities and Exchange Commission (the "**SEC**") on August 9, 2021, (ii) Current Reports on Form 8-K (the "**Current Reports**") filed with the SEC on August 9, 2021 and August 11, 2021. A copy of the Quarterly Report and the Current Reports is included below.

Investing in our securities involves risks that are described in the "*Risk Factors*" section beginning on page 11 of Prospectus #1 and page 8 of Prospectus #2.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this Supplement (or the Prospectuses including any supplements or amendments thereto) is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement is August 11, 2021.

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 **June 30, 2021**

or

☐ TRANSITION REPORT UNDER 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)

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

(Former name, former address, and former fiscal year, if changed since last report.): **N/A**

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging Growth Company	☒

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

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

The number of shares outstanding of the Registrant's Common Stock as of August 6, 2021 was 61,492,049.

CLENE INC.
Quarterly Report on Form 10-Q for the Period Ended June 30, 2021

PART I – FINANCIAL INFORMATION

Throughout this Quarterly Report on Form 10-Q (the "Quarterly Report"), the "Company," and references to "we," "us," or similar such references should be understood to be references to the combined company, Clene Inc. When this Quarterly Report references "Clene" and describes the business of Clene, it refers to the business of Clene Nanomedicine, Inc. and its subsidiaries, prior to the consummation of the business combination (referred to throughout as the "Reverse Recapitalization"). Following the date of the Reverse Recapitalization, references to "Clene" should be understood to reference Clene Inc. Given that the business combination is accounted for as a Reverse Recapitalization, as described in more detail below, and the accounting acquirer is Clene Nanomedicine, Inc., the post-Reverse Recapitalization financial statements included in this Quarterly Report show the condensed consolidated balances and transactions of the Company and Clene as well as comparative financial information of Clene (the acquirer for accounting purposes).

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 63,007	$ 59,275
Accounts receivable	68	21
Inventory	53	191
Prepaid expenses and other current assets	5,030	3,502
Total current assets	68,158	62,989
Right-of-use assets	983	1,029
Property and equipment, net	4,143	4,225
TOTAL ASSETS	$ 73,284	$ 68,243
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,143	$ 1,124
Accrued liabilities	2,731	3,960
Income tax payable	164	164
Deferred revenue from related parties	112	112
Operating lease obligations, current portion	210	194
Finance lease obligations, current portion	159	190
Clene Nanomedicine contingent earn-out, current portion	-	5,924
Total current liabilities	4,519	11,668
Operating lease obligations, net of current portion	1,658	1,785
Finance lease obligations, net of current portion	152	205
Convertible notes payable	4,380	-
Notes payable	10,378	1,949
Deferred income tax	140	260
Warrant liability	1,324	-
Clene Nanomedicine contingent earn-out, net of current portion	69,023	46,129
Initial Shareholders contingent earn-out	7,635	5,906
TOTAL LIABILITIES	99,209	67,902
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 150,000,000 and 100,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 60,681,591 and 59,526,171 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	6	6
Additional paid-in capital	170,449	153,571
Accumulated deficit	(196,668)	(153,561)
Accumulated other comprehensive income	288	325
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(25,925)	341
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 73,284	$ 68,243

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	138	9	337	79
Royalty revenue	63	-	77	-
Total revenue	201	9	414	79
Operating expenses:				
Cost of revenue	555	-	798	58
Research and development	6,472	3,554	12,747	6,756
General and administrative	6,949	1,016	12,339	1,828
Total operating expenses	13,976	4,570	25,884	8,642
Loss from operations	(13,775)	(4,561)	(25,470)	(8,563)
Other income (expense), net:				
Interest expense	(26)	(190)	(577)	(241)
Gain on extinguishment of notes payable	-	-	647	-
Gain on termination of lease	-	51	-	51
Change in fair value of preferred stock warrant liability	-	(2,419)	-	(2,307)
Change in fair value of derivative liability	-	10	-	14
Change in fair value of Clene Nanomedicine contingent earn-out	8,640	-	(16,970)	-
Change in fair value of Initial Shareholders contingent earn-out	1,232	-	(1,729)	-
Change in fair value of common stock warrant liability	133	-	133	-
Australia research and development credit	375	1,268	714	1,268
Other income (expense), net	(2)	22	1	18
Total other income (expense), net	10,352	(1,258)	(17,781)	(1,197)
Net loss before income taxes	(3,423)	(5,819)	(43,251)	(9,760)
Income tax benefit	72	-	144	-
Net loss	(3,351)	(5,819)	(43,107)	(9,760)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(61)	10	(37)	16
Total other comprehensive income (loss)	(61)	10	(37)	16
Comprehensive loss	(3,412)	(5,809)	(43,144)	(9,744)
Net loss per share-- basic and diluted (Note 19) [1]	(0.05)	(0.34)	(0.71)	(0.56)
Weighted average common shares used to compute basic and diluted net loss per share [1]	61,165,018	17,357,505	60,919,340	17,357,505

(1) Retroactively restated for the three months ended June 30, 2020 for the Reverse Recapitalization as described in Note 1

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)[(1)]

(Amounts in thousands, except share and per share amounts)

(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
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
Issuance of common stock upon vesting of restricted stock units	-	-	21,989	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	4,255	-	-	4,255
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)
Balances at December 31, 2019	27,499,837	$ 72,661	17,357,505	$ 2	$ 1,754	$ (69,571)	$ 41	$ (67,774)
Stock-based compensation expense	-	-	-	-	171	-	-	171
Foreign currency translation adjustment	-	-	-	-	-	-	6	6
Net loss	-	-	-	-	-	(3,941)	-	(3,941)
Balances at March 31, 2020	27,499,837	$ 72,661	17,357,505	$ 2	$ 1,925	$ (73,512)	$ 47	$ (71,538)
Stock-based compensation expense	-	-	-	-	174	-	-	174
Foreign currency translation adjustment	-	-	-	-	-	-	10	10
Net loss	-	-	-	-	-	(5,819)	-	(5,819)
Balances at June 30, 2020	27,499,837	$ 72,661	17,357,505	$ 2	$ 2,099	$ (79,331)	$ 57	$ (77,173)

(1) Retroactively restated for the Reverse Recapitalization as described in Note 1

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (43,107)	$ (9,760)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	499	463
Non-cash lease expense	46	66
Change in fair value of preferred stock warrant liability	-	2,307
Change in fair value of Clene Nanomedicine contingent earn-out	16,970	-
Change in fair value of Initial Shareholders contingent earn-out	1,729	-
Change in fair value of derivative	-	(14)
Change in fair value of common stock warrant liability	(133)	-
Gain on termination of lease	-	(51)
Stock-based compensation expense	7,520	345
Gain on extinguishment of notes payable	(647)	-
Loss on disposal	-	2
Accretion of debt discount	-	102
Increase in interest accrued on notes payable	389	118
Changes in operating assets and liabilities:		
Inventory	137	(31)
Accounts receivable	(48)	-
Prepaid expenses and other current assets	(1,528)	(1)
Accounts payable	565	1,044
Accrued liabilities	125	(71)
Deferred revenue from related parties	-	112
Deferred income tax	(119)	-
Payments of operating lease obligations	(111)	(33)
Net cash used in operating activities	(17,713)	(5,402)
Cash flows from investing activities:		
Purchases of property and equipment	(420)	(194)
Net cash used in investing activities	(420)	(194)
Cash flows from financing activities:		
Proceeds from exercise of stock options	108	-
Proceeds from issuance of convertible notes payable	-	3,125
Payments of deferred transaction costs	(1,901)	-
Payments of finance lease obligations	(83)	(109)
Proceeds from the private placement	9,250	-
Proceeds from the issuance of notes payable	15,000	652
Payments of debt issuance costs	(471)	
Payments of notes payable	(5)	-
Net cash provided by financing activities	21,898	3,668
Effect of foreign exchange rate changes on cash	(33)	29
Net increase (decrease) in cash	3,732	(1,899)
Cash – beginning of period	59,275	8,788
Cash – end of period	$ 63,007	$ 6,889
Supplemental disclosure of non-cash investing and financing activities:		
Warrant liability recorded at issuance of notes payable	$ 1,457	-
Acquisition of right-of-use assets and leasehold improvements through operating lease	$ -	$ 820
Lease liability settled through termination of lease	$ -	$ 349
Issuance of derivative instrument related to convertible notes	$ -	$ 374
Supplemental disclosure:		
Cash paid for interest expense	$ 188	$ 21

See accompanying notes to the condensed consolidated financial statements.

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

1. Nature of the Business

Clene Inc. (formerly Chelsea Worldwide Inc.) (the "**Company**," "**we**," "**us**," or similar such references) is a biopharmaceutical company focused on the development of clean-surfaced nanocrystal drugs. We have developed an electrocrystal chemistry drug development platform, in which nanocrystals within a suspension are the therapeutic drug. Utilizing technology to create nanocrystal drug suspensions, our platform has produced multiple drug assets, of which our lead assets are currently in development for use in neurological and infectious diseases, among others, such as a study for treatment of COVID-19 coronavirus pandemic. Secondary to our drug development, as part of our identification of potential drug assets, we have also identified certain mineral solutions as dietary supplements. Our dietary supplements may also be commercialized by a related party (see Note 20).

The accompanying condensed consolidated financial statements include the accounts of the Company 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, and dOrbital, Inc., a subsidiary incorporated in Delaware, after elimination of all intercompany accounts and transactions. The wholly-owned subsidiary, Clene Netherlands B.V. ("**Clene Netherlands**") was established on April 21, 2021 and has no financial positions or operations to date.

Registration Statements

On February 16, 2021, we filed a registration statement on Form S-1 (file number 333-253173) to register 4,541,481 shares of Clene Inc. common stock ("**Common Stock**") underlying outstanding warrants that we have previously issued, among which 2,517,500 and 904,231 warrants were originally issued by Tottenham Acquisition I Limited ("**Tottenham**" or "**TOTA**") and Clene Nanomedicine, respectively, prior to the closing of the Reverse Recapitalization, and 1,119,750 warrants were issued as part of a private placement (the "**PIPE**") in connection with the closing of the Reverse Recapitalization. We will receive aggregate proceeds of $30.7 million if all of these warrants are exercised. On April 19, 2021, the registration statement was declared effective by the Securities and Exchange Commission (the "**SEC**"). In connection with the registration statement on Form S-1, we incurred $0 and $27 thousand of certain offering costs during the three and six months ended June 30, 2021, respectively, recognized as an expense within general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss during the three and six months ended June 30, 2021.

On July 22, 2021, we filed a registration statement on Form S-1 (file number 333-258098) to register 1,140,731 shares of Common Stock underlying outstanding warrants that we have previously issued, among which 1,024,880 were originally issued by Clene Nanomedicine prior to the Reverse Recapitalization in April 2013 and 115,851 were issued pursuant to a loan agreement with Avenue Venture Opportunities Funds, L.P. (see Note 8). We will receive aggregate proceeds of $3.0 million if all of these warrants are exercised. In addition, the registration statement on Form S-1 registered 960,540 shares of Common Stock, issued in a private placement in May 2021, for possible sale by the selling shareholders. We will not receive any proceeds from the sale by the selling shareholders. On August 2, 2021, the registration statement was declared effective by the SEC. In connection with the registration statement on Form S-1, we incurred an immaterial amount of certain offering costs which will be recognized as an expense within general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss during the three and nine months ended September 30, 2021.

Liquidity

We have incurred significant losses and negative cash flows from operations since our inception. We incurred net losses of $3.4 million and $43.1 million for the three and six months ended June 30, 2021, respectively. We incurred net losses of $5.8 million and $9.8 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, our cash totaled $63.0 million, and our accumulated deficit was $196.7 million. As of December 31, 2020, our cash totaled $59.3 million, and our accumulated deficit was $153.6 million. We had net cash used in operating activities of $17.7 million and $5.4 million for the six months ended June 30, 2021 and 2020, respectively.

Prior to the Reverse Recapitalization, Clene Nanomedicine's operations were financed through the issuance of equity instruments and the issuance of convertible promissory notes. Subsequent to the Reverse Recapitalization, we have obtained additional liquidity through a term loan and private placements of equity instruments. We have not generated significant revenues to date and do not anticipate generating any significant revenues unless we successfully complete development and obtain regulatory approval for our drugs or for our COVID-19 study. We expect to incur additional losses in the future to fund our operations and conduct product research and development and we recognize the need to raise additional capital to fully implement our business plan. Additionally, we may attempt to negotiate a collaboration agreement with a third party for development and commercialization of a drug candidate, which may provide upfront and milestone payments to reduce our spending going forward.

We expect to continue investing in product development, sales and marketing and customer support for our products. 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.

We expect that the cash on hand as of June 30, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date these condensed consolidated financial statements are issued.

Impact of the COVID-19 Coronavirus 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 outbreak. The outbreak 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 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, delay the initiation of future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In particular, the Company and our clinical research organizations ("**CROs**") may face disruptions that may affect our ability to initiate and complete preclinical studies, manufacturing disruptions, and delays at clinical trial sites. The 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 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 and financial statements. While the COVID-19 pandemic has led to various research restrictions and paused 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 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, results of operations, cash flows, and financial condition, 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

We have prepared the accompanying condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("**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 include only normal recurring adjustments, necessary for a fair statement of our financial position as of June 30, 2021, the results of our operations for the three and six months ended June 30, 2021, our cash flows for the six months ended June 30, 2021 and 2020, and the condensed consolidated statement of stockholders' equity (deficit) for the three and six months ended June 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2021 and 2020 are unaudited. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period.

Prior period balances for accounts receivable have been reclassified to conform to the current year presentation.

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 at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited, to the valuation of common stock, stock options, contingent earn-out liabilities, Preferred Stock warrants, and Common Stock warrants.

We base our estimates on historical experience and on various other assumptions that are believed 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. Changes in estimates will be recorded in future periods as they develop.

Risks and Uncertainties

The product candidates we develop require approvals from the U.S. Food and Drug Administration or foreign 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 risks common to companies in the development stage including, but not limited to, dependency on the need for substantial additional financing to achieve our goals, uncertainty of broad adoption of our approved products, if any, by physicians and patients, significant competition, and untested manufacturing capabilities.

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 position or results of operations: 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 an original maturity of three months or less when purchased to be cash equivalents. As of June 30, 2021 and December 31, 2020, we had no cash equivalents and no restricted cash balances.

Accounts Receivable

Accounts receivable are stated at invoice value less estimated allowances for sales returns and doubtful accounts. We estimate the allowance for sales returns based on historical percentage of returns over a 12-month trailing average of sales. We continually monitor customer payments and maintain a reserve for estimated losses resulting from our customers' inability to make required payments. We consider factors when estimating the allowance for doubtful accounts such as historical experience, age of the accounts receivable balances, geographic related risks, and economic conditions that may affect a customer's ability to pay. In cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, a specific allowance is recorded against amounts due, thereby reducing the net recognized receivable to the amount reasonably believed to be collectible. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received. Historically, there have been no sales returns, no written-off accounts receivable, and no allowance for doubtful accounts reducing the balance of the accounts receivable.

Inventory

Inventory is stated at historic cost on a first-in first-out basis. Our inventory consisted of $27 thousand in raw materials and $27 thousand in finished goods as of June 30, 2021. Our inventory consisted of $0.1 million in raw material and $0.1 million in finished goods as of December 31, 2020.

Debt Discounts, Debt Premiums, and Debt Issuance Costs

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

Leases

At inception of a contract, we determine if a contract meets the definition of a lease. A lease is a contract, or part of a contract, that conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. We determine if the contract conveys the right to control the use of an identified asset for a period of time. We assess throughout the period of use whether we have both of the following: (1) the right to obtain substantially all of the economic benefits from use of the identified asset, and (2) the right to direct the use of the identified asset. This determination is reassessed if the terms of the contract are changed. Leases are classified as operating or finance leases based on the terms of the lease agreement and certain characteristics of the identified asset. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments.

We lease laboratory and office space and certain 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. Our policy is to not record leases with an original term of twelve months or less on the condensed consolidated balance sheets. We recognize lease expense for these short-term leases on a straight-line basis over the lease term.

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

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

Property and Equipment

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

Convertible Notes

In accordance with ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, when we issue notes with conversion features, we evaluate if the conversion features are freestanding or embedded. If the conversion feature is embedded, we do not separate the conversion feature from the host contract for convertible notes that are not required to be accounted for as derivatives, or that do not result in substantial premiums accounted for as paid-in-capital. Consequently, we account for a convertible note as a single liability measured at its amortized cost, and we account for a convertible preferred stock as a single equity instrument measured at its historical cost, as long as no other features require bifurcation and recognition as derivatives.

If the conversion feature is freestanding, or is embedded and meets the requirements to be bifurcated, we account for the conversion feature as a derivative under ASC 815, *Derivatives and Hedging* ("**ASC 815**"). We record the derivative instrument at fair value at inception, and subsequently re-measure to fair value at each reporting period and immediately prior to the extinguishment of the derivative instrument, with any changes recorded in the condensed consolidated statements of operations and comprehensive loss.

Debt With Warrants

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

Contingent Earn-out Liabilities

In connection with the Reverse Recapitalization, certain shareholders are entitled to receive additional shares of Common Stock (the "**Contingent Earn-outs**") upon us achieving certain milestones (see Notes 3 and 12). In accordance with 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 in the condensed consolidated statements of operations and comprehensive loss.

The estimated fair value of the Contingent Earn-outs is determined using a Monte Carlo simulation that simulates the future path of our Common Stock price over the earn-out periods. The assumptions utilized in the calculation are based on the achievement of certain stock price milestones including projected stock price, volatility, and risk-free rate. For potential payments related to a product development milestone, the fair value is determined based on our expectations of achieving such a milestone and the simulated estimated stock price on the expected date of achievement.

The Contingent Earn-outs are categorized as Level 3 fair value measurements (see Fair Value of Financial Instruments accounting policy) because we estimate projections during the earn-out period utilizing unobservable inputs, including various potential pay-out scenarios. Contingent earn-out payments involve certain assumptions requiring significant judgment and actual results may differ from assumed and estimated amounts.

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 in accordance with ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our Common Stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and, for liability-classified warrants, as of each subsequent quarterly period end date while the warrants are outstanding.

Revenue Recognition

Under ASC 606, *Revenue from Contracts with Customers* ("**ASC 606**"), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver, and which performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. We typically satisfy our performance obligations via delivery of dietary supplements to the customer. Payments are due upon receipt for commercial transactions, or a prepayment is collected for online retail sales. Our revenue for the three and six months ended June 30, 2021 and 2020 was comprised of sales of dietary supplements.

We recorded deferred revenue of $0.1 million and $0.1 million as of June 30, 2021 and December 31, 2020 from the dietary supply agreement with the related party (see Note 20). The deferred revenue at December 31, 2020 is expected to be recognized in the third quarter of 2021.

Grant Funding

We may submit applications to receive grant funding from governmental and non-governmental entities. Grant funding received that involves no conditions or continuing performance obligations of the Company is recognized upon receipt. Grant funding with conditions or obligations of the Company is recognized as the conditions or obligations are fulfilled. We have made an accounting policy election to record such unconditional grants, such as the Australian Research and Development Credit, as other income in the condensed consolidated statements of operations and comprehensive loss. 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 recognize the Australian Research and Development Credit in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. During the three and six months ended June 30, 2021, we recognized $0.4 million and $0.7 million, respectively, of Australian Research and Development Credit within other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. During the three and six months ended June 30, 2020, we recognized $1.3 million and $1.3 million, respectively, of Australian Research and Development Credit within other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. As of June 30, 2021, and December 31, 2020, we recorded $2.7 million and $2.1 million, respectively, of Australian Research and Development Credit receivable in prepaid expenses and other current assets on the condensed consolidated balance sheets.

Any amount received in advance of fulfilling such conditions or obligations is recorded in accrued liabilities on the condensed consolidated balance sheets if the conditions or obligations are expected to be met within the next twelve months. As of June 30, 2021 and December 31, 2020, we recorded $0.4 million and $0.3 million, respectively, of deferred grant funds received in advance in accrued liabilities.

Grant funding recognized on conditional grants is included as a reduction in research and development expenses in the condensed consolidated statements of operations and comprehensive loss as the conditions are tied to our research and development efforts, and as the arrangement between us and the organizations are not part of our ongoing, major, or central operations. During the three and six months ended June 30, 2021, we recorded a grant of $0.2 million and $0.2 million, respectively, as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive loss. During the three and six months ended June 30, 2020, we recorded a grant of $0.2 million and $0.4 million, respectively, as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive loss.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy:

Level 1 — Inputs based upon quoted market prices for identical assets or liabilities in active markets at the measurement date.

Level 2 — Observable inputs other than quoted market prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Inputs that are management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. The inputs are unobservable in the market and significant to the instrument's valuation.

We review the fair value hierarchy classification of our applicable assets and liabilities on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. Reclassifications impacting all levels of the fair value hierarchy are reported as transfers in or out of the Level 1, 2, or 3 categories as of the beginning of the quarter during which the reclassifications occur.

Foreign Currency Translation and Transactions

Our functional currency is the United States ("**U.S.**") dollar. Our Australian subsidiary determined its functional currency to be the Australian dollar and our Netherlands subsidiary 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 shareholders' 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 shareholders' equity. These foreign currency translation gains and losses are currently the only component of other comprehensive income (loss).

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) in the condensed consolidated statements of operations and comprehensive loss as incurred.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The only element of other comprehensive income (loss) in any period presented was translation of Australian dollar denominated balances of our Australian subsidiary to U.S. dollars for consolidation.

Net Loss Per Share Attributable to Common Shareholders

We calculated basic and diluted net loss per share attributable to common shareholders in conformity with the two-class method required for companies with participating securities. We considered all series of redeemable convertible Preferred Stock to have been participating securities as the holders were entitled to receive non-cumulative dividends on a pari passu basis in the event that a dividend had been paid on Common Stock. See Note 19, *Net Loss Per Share Attributable to Common Shareholders*, for further details on our historical participating securities, including warrants to purchase redeemable convertible Preferred Stock and Common Stock.

Under the two-class method, basic net loss per share attributable to common shareholders was calculated by dividing the net loss by the weighted-average number of shares of Common Stock outstanding during the period, less shares subject to repurchase. Diluted net loss per share attributable to common shareholders was computed by giving effect to all potentially dilutive common stock equivalents outstanding for the period. For purposes of this calculation, redeemable convertible Preferred Stock, stock options to purchase Common Stock, early exercised stock options, and warrants to purchase redeemable convertible Preferred Stock and Common Stock were considered common shares equivalents but had been excluded from the calculation of diluted net loss per share attributable to common shareholders as their effect was anti-dilutive. In periods in which we report a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is the same as basic net loss per share attributable to common shareholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. We reported a net loss attributable to common shareholders during the three and six months ended June 30, 2021 and 2020.

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: (1) the development and commercialization of proprietary nanotechnology drug suspensions ("**Drugs**"), and (2) the development and commercialization of dietary supplements ("**Supplements**"). 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 (see Note 21).

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, that are considered appropriate as well as the related net interest and penalties.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees using a fair value-based method for costs related to all share-based payments including stock options and restricted stock units ("**RSUs**"). 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.

Prior to the Reverse Recapitalization, there was not a public market for the shares of Clene Nanomedicine common stock. Our determination of the fair value of stock options on the date of grant utilized the Black-Scholes valuation model and was impacted by its common stock price, as determined by the Board of Directors with input from management, as well as changes in assumptions regarding a number of subjective variables. These variables included, but were not limited to, the expected term that options remained outstanding, the expected common stock price volatility over the term of the option awards, risk-free interest rates, and expected dividends.

The fair value was recognized over the period during which a grantee was required to provide services in exchange for the option award and service-based RSUs, known as the requisite service period (usually the vesting period), on a straight-line basis. For RSUs 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 RSUs 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.

Stock-based compensation expense is recognized at fair value. We elect to account for forfeitures as they occur, rather than estimating expected forfeitures.

After the closing of the Reverse Recapitalization, we determine the fair value of each share of Common Stock underlying stock-based awards based on the closing price of our Common Stock as reported by the Nasdaq Stock Exchange ("**Nasdaq**") on the date of grant. The fair value of RSUs with market conditions are determined using a Monte Carlo valuation model.

Research and Development

Research and development costs are charged to expense as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed. Research and development expenses consist of costs incurred for the discovery and development of our product candidates. Research and development costs include, but are not limited to, payroll and personnel expenses including stock-based compensation, clinical trial supplies, fees for clinical trial services, consulting costs, and allocated overhead, including rent, equipment, and utilities.

Clinical Trial Accrual

Our clinical trial accrual process accounts for expenses resulting from obligations under contracts with CROs, consultants, and under clinical site agreements in connection with conducting clinical trials. Clinical trial costs are charged to research and development expense as incurred. 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 clinical trial expense 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 amortized to research and development expense over the period the contracted services are performed. In addition to pass-through costs, we generally incur costs in clinical trials in four distinct groups as follows:

CRO Start-up — These costs include the initial set-up of the clinical trial and usually occur within a few months after the contract has been executed and includes costs which are expensed ratably over the start-up period when such period is identifiable and expensed as incurred when no such period exists. Start-up phase activities include study initiation, site recruitment, regulatory applications, investigator meetings, screening, preparation, pre-study visits, and training.

CRO Site and Study Management — These costs include medical and safety monitoring, patient administration and data management. These costs are usually calculated on a per-patient basis and expensed ratably over the treatment period beginning on the date that the patient enrolls.

CRO Close-Down and Reporting — These costs include analyzing the data obtained and reporting results, which occurs after patients have ceased treatment and the database of information collected is locked. These costs are expensed as incurred over the course of any close-down and reporting period.

Third-Party Contracts — These costs include fees charged by third parties for various support services which are not provided by CROs and include such items as lab fees, data quality review costs, and fees incurred for investigational product monitoring and inventory control. These items are expensed ratably over any identifiable service period with the engaged third-party vendors.

The CRO contracts generally include pass-through fees including, but not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We determine accrual estimates through reports from and discussion with applicable personnel and outside service providers as to the progress or state of completion of trials or the services completed. We estimate accrued expenses as of each balance sheet date in the condensed consolidated financial statements based on the facts and circumstances known to us at that time.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 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* to simplify accounting for certain financial instruments by removing certain separation models for convertible instruments. Under the amendments in ASU 2020-06, the embedded conversion features no longer are separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives, or that do not result in substantial premiums accounted for as paid-in-capital. Consequently, a convertible debt instrument will be accounted as a single liability measured at its amortized cost, and a convertible preferred stock will be accounted for as a single equity instrument measured at its historical cost, as long as no other features require bifurcation and recognition as derivatives. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirements to use the if-converted method for all convertible instruments. The new guidance is effective for fiscal years beginning after December 15, 2023, and should be applied on a full or modified retrospective basis, with early adoption permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods with those fiscal years. We early adopted ASU 2020-06 on January 1, 2021. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions in which the reference LIBOR or another reference rate is expected to be discontinued as a result of the Reference Rate Reform. This ASU is intended to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. The new guidance was effective immediately, and through December 31, 2022. As a result of our election to utilize the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-02 is effective for our fiscal years beginning after December 15, 2020, and all interim periods thereafter. Early adoption is permitted. We early adopted this guidance on March 1, 2020. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*. The new guidance provides for the deferral of implementation costs for cloud computing arrangements and expensing those costs over the term of the cloud services arrangement. The new guidance was effective for fiscal years beginning after December 15, 2020. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The amendments in this ASU, 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 of the new guidance as a result of this extended deadline of implementation for smaller reporting companies.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)*, which amends the existing guidance relating to the accounting for income taxes. This ASU is intended to simplify the accounting for income taxes by removing certain exceptions to the general principles of accounting for income taxes and to improve the consistent application of GAAP for other areas of accounting for income taxes by clarifying and amending existing guidance. As a smaller reporting company, the guidance is effective for our fiscal years beginning after December 15, 2021. We do not expect that the adoption of this new guidance will have a material impact on our condensed consolidated financial statements.

3. Reverse Recapitalization with Tottenham and Clene Nanomedicine

On December 30, 2020 (the "**Closing Date**"), Chelsea Worldwide Inc., our predecessor company, consummated the previously announced business combination (referred to as the "**Reverse Recapitalization**") pursuant to a merger agreement, dated as of September 1, 2020 (the "**Merger Agreement**"), by and among Clene Nanomedicine, 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 shareholders. Prior to the Reincorporation Merger discussed below, 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.

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**"); (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."

Upon the consummation of the Reverse Recapitalization, each Tottenham ordinary share issued and outstanding immediately prior to the effective time of the Reincorporation Merger, which totaled 2,303,495 shares held by the Initial Shareholders and Tottenham public shareholders (excluding certain shares that were canceled pursuant to the Merger Agreement, any redeemed shares, and any dissenting shares), was automatically cancelled and ceased to exist and (i) for each Tottenham ordinary share, we issued to each shareholder one validly-issued share of our Common Stock; (ii) each warrant to purchase one-half (1/2) of one Tottenham Ordinary Share converted into a warrant to purchase one-half (1/2) of one share of our Common Stock; (iii) each right exchangeable into one-tenth (1/10) of one Tottenham ordinary share converted into a right exchangeable for one-tenth (1/10) of one share of our Common Stock; provided, however, that no fractional shares were issued and all fractional shares were rounded down to the nearest whole share. In addition, pursuant to the Merger Agreement, the Initial Shareholders are entitled to receive up to 750,000 shares of Common Stock as earn-out shares upon the achievement of certain milestones described below.

On the Closing Date, each share of Clene Nanomedicine common stock then issued and outstanding was cancelled and the holders thereof in exchange received 54,339,012 shares of Clene Inc. Common Stock, which is equal to 0.1389 newly-issued shares of Clene Inc. Common Stock for each single share of Clene Nanomedicine common stock (the "**Exchange Ratio**"). Pursuant to the Merger Agreement, 5% of the aggregate amount of the closing payment shares, or 2,716,958 shares were held in escrow to satisfy any indemnification obligation incurred and were released six months after the closing of the Reverse Recapitalization. In addition, each share of Clene Nanomedicine's preferred stock outstanding immediately prior to the closing of the Reverse Recapitalization was converted into the right to receive our Common Stock based on the same Exchange Ratio. All outstanding warrants exercisable for common stock in Clene Nanomedicine (other than warrants that expired, were exercised or were deemed automatically net exercised immediately prior to the Acquisition Merger) were exchanged for warrants exercisable for our Common Stock with the same terms and conditions except adjusted by the Exchange Ratio. All outstanding stock options of Clene Nanomedicine common stock, totaling 53,286,115 stock options, was cancelled and the holders thereof in exchange received 0.1320 newly issued stock options of our Common Stock for a total of 7,032,591 stock options, which is 95% of the Exchange Ratio. Pursuant to the Merger Agreement, we issued 370,101 RSUs to the option holders which complements the 5% closing payment shares held in escrow for Clene Nanomedicine common shareholders. The modification of the stock options did not result in a material incremental compensation expense upon closing of the Reverse Recapitalization.

In addition, we issued 1,136,961 RSUs to option holders to complement the earn-out payments that would contingently be issued to certain current Clene Nanomedicine's shareholders upon the achievement of milestones described below.

The proceeds received from the Reverse Recapitalization were $3.7 million, net of offering costs of $5.9 million which excludes the fair value of common shares issued as a payment of related offering costs.

In connection with Tottenham's initial public offering in August 2018, Tottenham issued to Chardan Capital Markets, LLC ("**Chardan**"), options to purchase 220,000 units at $11.50 per unit. Each of the units consists of one and one-tenth shares of Tottenham's ordinary shares and one warrant to purchase one-half of one of Tottenham's ordinary shares at an exercise price of $11.50 per share (the "**Chardan Unit Purchase Option**"). In connection with the Reverse Recapitalization, the Chardan Unit Purchase Option was converted into one Company unit purchase option. The warrants included in the Chardan Unit Purchase Option (the "**Chardan Unit Purchase Option Warrants**") are exercisable upon the completion of the Reverse Recapitalization and will expire on December 30, 2025, five years after the consummation of the Reverse Recapitalization (see Note 10).

Also, in connection with the Reverse Recapitalization, Clene Nanomedicine entered into a letter agreement with LifeSci Capital LLC ("**LifeSci**") on July 2, 2020, according to which LifeSci was engaged to act as Clene Nanomedicine's financial advisor with respect to identifying and soliciting special purpose acquisition companies for the purpose of entering into a merger or similar transaction with Clene Nanomedicine and its shareholders. Under this agreement, Clene Nanomedicine agreed that if it consummated a merger with Tottenham, LifeSci would receive consideration of (i) 3% of the amount by which the total transaction consideration exceeded $350 million, plus (ii) 7% of cash and cash-equivalents received by Clene Nanomedicine from the Tottenham's trust account. Clene Nanomedicine could elect to pay LifeSci either in cash, equity interests of the surviving company, or a combination of the two. Upon the consummation of the Reverse Recapitalization, 644,164 shares of Common Stock were issued to LifeSci as consideration for its services as pursuant to the letter agreement (see Note 18).

Immediately after giving effect to the Reverse Recapitalization, there were 59,526,171 shares of Common Stock issued and outstanding and warrants to purchase 5,566,363 shares of Common Stock issued and outstanding (see Note 10). Based on the number of shares of Common Stock outstanding on December 30, 2020 (in each case, not giving effect to any shares issuable upon exercise of warrants, options, or earn-out shares), Clene Nanomedicine's shareholders owned approximately 91% of the Common Stock of the Company, Tottenham shareholders owned approximately 4% of the Common Stock of the Company, and investors from the PIPE owned approximately 4% of the Common Stock of the Company.

During Tottenham's IPO, Tottenham incurred deferred underwriters' fees which were payable to Chardan from the amounts held in the trust account upon completion of the Reverse Recapitalization. Upon the closing of the Reverse Recapitalization, we paid $2.1 million to Chardan as settlement of the deferred underwriting fees which amount was included in the total offering costs of the Reverse Recapitalization transaction.

During the year ended December 31, 2020, we recorded $5.9 million of offering costs related to third-party legal, accounting, and other professional services to consummate the Reverse Recapitalization, excluding the fair value of common shares issued as a payment of related offering costs and Chardan underwriting fees discussed above. These offering costs are recorded as a reduction of additional paid-in capital upon the close of the Reverse Recapitalization in our condensed consolidated balance sheets.

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 shareholders have a majority of the voting power of the combined company, Clene Nanomedicine comprises all of the ongoing operations of the combined entity, Clene Nanomedicine comprises a majority of the governing body of the combined company, and Clene Nanomedicine's senior management comprises all of the senior management of the combined 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. The shares and net loss per common share, prior to the Reverse Recapitalization, have been retroactively restated as shares reflecting the Exchange Ratio established in the Reverse Recapitalization. The net assets of Tottenham were recorded at historical costs, with no goodwill or other intangible assets recorded. Operations prior to the Reverse Recapitalization are those of Clene Nanomedicine.

Earn-out Shares

Certain of Clene Nanomedicine's current shareholders are entitled to receive earn-out shares as follows (the "**Clene Nanomedicine Contingent Earn-out**"): (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 (or any foreign currency equivalent) (the "**Milestone 1 Price**") in any twenty trading days within a thirty trading day period within the three years following the closing of the Reverse Recapitalization on any securities exchange or securities market on which the shares of our Common Stock are then traded or (B) the change of control price equals or exceeds the Milestone 1 Price if a change of control transaction occurs within the three years following the closing of the Reverse Recapitalization (the requirements set forth in clause (A) and (B), "**Milestone 1**"); (ii) 2,500,000 shares of Common Stock if (A) the VWAP of the shares of our Common Stock equals or exceeds $20.00 (or any foreign currency equivalent) (the "**Milestone 2 Price**") in any twenty trading days within a thirty trading day period within the five years following the closing of the Reverse Recapitalization on any securities exchange or securities market on which the shares of our Common Stock are then traded or (B) the change of control price equals or exceeds the Milestone 2 Price if a change of control transaction occurs within the five years following the closing of the Reverse Recapitalization (the requirements set forth in clause (A) or (B), "**Milestone 2**"); and (iii) 2,500,000 shares of Common Stock if Clene Nanomedicine completes a randomized placebo-controlled study for treatment of COVID-19 which results in a statistically significant finding of clinical efficacy within twelve months after the closing of the Reverse Recapitalization ("**Milestone 3**"). If Milestone 1 is not achieved but Milestone 2 is achieved, the Clene Nanomedicine shareholders will receive a catch-up issuance equal to the shares issued upon satisfaction of Milestone 1. Upon the consummation of the Reverse Recapitalization, the Clene Nanomedicine Contingent Earn-out shares increased by 12,852 as a result of the exercise of stock options during November 2020. Therefore, the total Clene Nanomedicine Contingent Earn-out shares has increased to 8,346,185 shares of Common Stock.

The Initial Shareholders of Tottenham may be entitled to receive earn-out shares as follows (the "**Initial Shareholders Contingent Earn-out**"): (i) 375,000 shares of Common Stock upon satisfaction of the requirements of Milestone 1; and (ii) another 375,000 shares of the Company's Common Stock upon satisfaction of the requirements of Milestone 2. If Milestone 1 is not achieved but Milestone 2 is achieved, the Initial Shareholders shall receive a catch-up issuance equal to the shares granted upon satisfaction of the requirements of Milestone 1.

The Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out (collectively, 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 (see Note 16).

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following as of June 30, 2021 and December 31, 2020:

(in thousands)	**June 30, 2021**	**December 31, 2020**
Australia research and development credit receivable	$ 2,734	$ 2,148
CRO prepayments	579	1,211
Metals to be used in research and development	614	31
Directors & Officers Insurance	936	-
Other	167	112
	$ 5,030	$ 3,502

5. Property and Equipment, Net

Property and equipment, net consisted of the following as of June 30, 2021 and December 31, 2020:

(in thousands)	June 30, 2021	December 31, 2020
Lab equipment	$ 3,107	$ 3,077
Furniture and fixtures	147	147
Leasehold improvements	3,927	3,889
Construction in progress	821	490
	8,002	7,603
Less accumulated depreciation	(3,859)	(3,378)
Total property and equipment, net	$ 4,143	$ 4,225

Depreciation expense related to property and equipment, net for the three and six months ended June 30, 2021 was approximately $0.2 million and $0.5 million, respectively. Depreciation expense is reported in research and development expense and in general and administrative expense for $0.4 million and $0.1 million, respectively, for the six months ended June 30, 2021; and in research and development expense and in general and administrative expense for $0.2 million and $29 thousand, respectively, for the three months ended June 30, 2021, in the condensed consolidated statements of operations and comprehensive loss.

Depreciation expense related to property and equipment, net for the three and six months ended June 30, 2020 was approximately $0.2 million and $0.5 million, respectively. Depreciation expense is reported in research and development expense and in general and administrative expense for $0.5 million and $13 thousand, respectively, for the six months ended June 30, 2020; and in research and development expense and in general and administrative expense for $0.2 million and $12 thousand, respectively, for the three months ended June 30, 2020, in the condensed consolidated statements of operations and comprehensive loss.

6. Accrued Liabilities

Accrued liabilities consisted of the following as of June 30, 2021 and December 31, 2020:

(in thousands)	June 30, 2021	December 31, 2020
Accrued professional fees	$ -	$ 189
Accrued compensation and benefits	1,533	1,225
Accrued CRO fees	691	788
Deferred grant funds	351	301
Accrued expense reimbursements	33	33
Accrued transaction costs	-	1,354
Other	123	70
	$ 2,731	$ 3,960

7. Leases

We adopted ASC 842, *Leases* on January 1, 2019 using the modified retrospective approach.

We also made an accounting policy election not to recognize leases with an initial term of 12 months or less within our condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis in our condensed consolidated statements of operations and comprehensive loss over the lease term.

At the lease commencement date, the discount rate implicit in the lease is used to discount the lease liability if readily determinable. If not readily determinable or leases do not contain an implicit rate, our incremental borrowing rate is used as the discount rate.

In April 2020, we terminated an existing operating lease for office space. At the time of termination, we removed the remaining right-of-use asset of $0.3 million, lease liability of $0.3 million, and recognized a gain of $0.1 million. Further, in April 2020, we commenced a new operating lease. At the time of commencement, we recorded the right-of-use asset value of $0.4 million, leasehold improvements of $0.4 million, and a lease liability of $0.8 million. The net effect of the change in leases being an increase in right-of-use assets of $0.1 million, an increase in leasehold improvements of $0.5 million, an increase in lease liability of $0.4 million, and a gain on termination of $0.1 million.

We have noncancelable operating lease arrangements primarily for office and lab space. We also have noncancelable finance leases for certain lab equipment. The maturity analysis of finance and operating lease liabilities as of June 30, 2021 are as follows:

(in thousands)	Finance Leases	Operating Leases
2021 (remainder)	$ 76	172
2022	135	421
2023	82	433
2024	21	442
2025	-	454
2026	-	466
Thereafter	-	63
Total undiscounted cash flows	314	2,451
Less amount representing interest/discounting	(3)	(583)
Present value of future lease payments	311	1,868
Less lease obligations, current portion	(159)	(210)
Lease obligations – long term portion	$ 152	$ 1,658

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

Finance Leases

Assets recorded under finance lease obligations and included with property and equipment as of June 30, 2021 and December 31, 2020 are summarized as follows:

(in thousands)	June 30, 2021	December 31, 2020
Lab equipment	$ 920	$ 920
Furniture and fixtures	46	46
Work in process	228	228
Total	1,194	1,194
Less accumulated depreciation	(666)	(593)
Net	$ 528	$ 601

As of June 30, 2021, our finance lease obligations had a weighted-average interest rate of 8.4% and had a weighted-average remaining term of 2.5 years. As of December 31, 2020, our finance lease obligations had a weighted-average interest rate of 8.1% and had a weighted-average remaining term of 2.7 years.

Operating Leases

Our balance of right-of-use assets on the face of the balance sheet pertain to operating leases. As of June 30, 2021, our operating lease obligations had a weighted-average discount rate of 9.6% and had a weighted-average remaining term of 6.3 years. As of December 31, 2020, our operating lease obligations had a weighted-average discount rate of 9.6% and a weighted-average remaining term of 6.3 years.

Components of Lease Cost

The components of finance and operating lease costs for the three and six months ended June 30, 2021 and 2020 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Finance lease costs:				
Amortization	$ 36	$ 48	$ 73	$ 96
Interest on lease liabilities	7	10	15	21
Operating lease costs	70	132	140	213
Short-term lease costs	54	49	116	137
Variable lease costs	20	14	39	48
Total lease costs	$ 187	$ 253	$ 383	$ 515

Supplemental Cash Flow Information

(in thousands)	**2021**	**2020**
Operating cash flows from operating leases	$ (295)	$ (338)
Operating cash flows from finance leases	$ (15)	$ (21)
Financing cash flows from finance leases	$ (83)	$ (109)

8. Notes Payable

Maryland Loan

In February 2019, we entered into a loan agreement (the "**2019 MD Loan**") with the Department of Housing and Community Development, a principal department of the State of Maryland ("**Maryland**"). Pursuant to the 2019 MD Loan, Maryland agreed to provide a $0.5 million term loan. Amounts outstanding under the 2019 MD Loan bear simple interest at an annual rate of 8.00%. Under the 2019 MD Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include 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 Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on February 22, 2034. The 2019 MD Loan establishes "Phantom Shares," based on 119,906 shares of Common Stock (based on 863,110 Series C Preferred Shares prior to the Reverse Recapitalization), determined at issuance. The Loan Agreement states the repayment amount is to be the greater of the balance of principal and accrued interest or the Phantom Shares value. We determined that the note should be accounted for at fair value. We record the fair value of the debt at the end of each reporting period. In order to value the note, we consider the amount of the simple interest expense that would be due and the value of Phantom Shares. Upon the closing of the Reverse Recapitalization and as of December 31, 2020, the fair value of the 2019 MD Loan is determined based on the closing price of CLNN shares listed on Nasdaq. Income of $0.2 million and expense of $0.3 million was recognized during the three and six months ended June 30, 2021, respectively. Expense of $0.1 million and $0.1 million was recognized during the three and six months ended June 30, 2020, respectively. The fair value of $1.3 million and $1.1 million of principal and accrued interest is included in long-term notes payable as of June 30, 2021 and December 31, 2020, respectively.

Cecil County Loan

In April 2019, we entered into a loan agreement (the "**2019 Cecil Loan**") with Cecil County, Maryland ("**Cecil**"). Pursuant to the 2019 Cecil Loan, Cecil agreed to provide a $0.1 million term loan. Amounts outstanding under the 2019 Cecil Loan bear simple interest at an annual rate of 8.00%. Under the 2019 Cecil Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include 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 Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on April 30, 2034. The 2019 Cecil Loan establishes "Phantom Shares," based on 23,981 shares of Common Stock (based on 172,622 Series C Preferred Shares prior to the Reverse Recapitalization), determined at issuance. The 2019 Cecil Loan states the repayment amount is to be the greater of the balance of principal and accrued interest or the Phantom Share value. We determined that the note should be accounted for at fair value. We record the fair value of the debt at the end of each reporting period. In order to value the note, we consider the amount of the simple interest expense that would be due and the value of Phantom Shares. Upon the closing of the Reverse Recapitalization and as of December 31, 2020, the fair value of the 2019 Cecil Loan is determined based on the closing price of CLNN shares listed on Nasdaq. Income of $36 thousand and expense of $0.1 million was recognized during the three and six months ended June 30, 2021, respectively. Expense of $11 thousand and $13 thousand was recognized during the three and six months ended June 30, 2020, respectively. The fair value of $0.3 million and $0.2 million of principal and accrued interest is included in long-term notes payable as of June 30, 2021 and December 31, 2020, respectively.

PPP Loan

In May 2020, we entered into a note payable in the amount of $0.6 million (the "**PPP Note**") under the Paycheck Protection Program of the CARES Act (the "**PPP**"). As amended, the PPP permits forgiveness of amounts loaned for payments of payroll and other qualifying expenses within 24 weeks of receipt of loaned funds, given that at least 60% of the total loan is used for payroll. Amounts not forgiven have a repayment period of five years. In January 2021, the full $0.6 million balance of the PPP Note was forgiven and has been recorded as a gain on extinguishment of debt during the six months ended June 30, 2021. There was no gain on extinguishment of debt recorded during the three months ended June 30, 2021.

Avenue Loan

In May 2021, we entered into a loan agreement (the "**2021 Avenue Loan**") with Avenue Venture Opportunities Funds, L.P. ("**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. We incurred issuance costs for a total of $0.5 million of which $35 thousand have been expensed immediately. The remaining balance from Tranche 1 of $5.0 million and an additional tranche of $10.0 million ("**Tranche 2**") are available at the Company's request until December 31, 2021 and June 30, 2022, respectively. Funding of the remainder of Tranche 1 and entire Tranche 2 is subject to evidence reasonably satisfactory of receipt of an additional $5.0 million financing through Maryland's State Incentive Programs and/or other Maryland State programs and mutual agreement of the Company and Avenue. Funding of Tranche 2 is also subject to (i) our achievement of a statistically significant result on the primary endpoint as defined within the statistical analysis plan for each respective study, or the totality of the results for any study warrant advancement into a subsequent clinical efficacy study, as reasonably determined by the Company and Avenue with respect to at least two of the following studies: (i) RESCUE-ALS or HEALEY-ALS; (ii) REPAIR-PD; or (iii) REPAIR- MS ("**Performance Milestone 1**"); and (ii) our receipt of net proceeds of at least $30 million from the sale and issuance of our equity securities (including any private placement or follow-on offering) between May 2, 2021 and June 30, 2022.

The term loan bears interest of 9.85%. Interest is the higher of the prime rate plus 6.60% or 9.85%. Payments for the loan are interest only for the initial 12 months and can be extended to (i) 12 months (the "**First Interest-only Period Extension**") if we achieve Performance Milestone 1 and (ii) up to 36 months if we achieve the First Interest-only Period Extension and draw Tranche 2. The loan will amortize in equal payments of principal 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, or $0.6 million, is due in addition to the remaining unpaid principal and accrued interest. The final payment is recorded as a debt premium and is being amortized over the contractual term using the effective interest method. The final payment provision is related to the loan host and is not bifurcated pursuant to ASC 815.

Pursuant to the agreement, we granted to Avenue a warrant for the purchase of 115,851 shares of Common Stock at an exercise price equal to the lower of (i) $8.63 (which is equal to the five-day VWAP per share, determined as of the end of trading on the last trading day prior to execution of the loan agreement), or (ii) the lowest price per share paid by cash investors for our Common Stock issued in the next bona fide round of equity financing prior to March 31, 2022 (the "**Next Round Price**") (see Note 10). Upon the funding of Tranche 2, the warrant shall be automatically adjusted to include an additional 72,226 shares of Common Stock, which is equal to 5% of the principal amount of Tranche 2, divided by the lower of (i) the five (5)-day VWAP per share; determined as of the end of trading on the last trading day before the date of issuance of Tranche 2; or (ii) the Next Round Price. We accounted for the Tranche 2 warrants at inception of the 2021 Avenue Loan in accordance with ASC 815 (see Note 1 and Note 10). Avenue also has the right, in its discretion, but not the obligation, at any time from time to time from the first through the third-year anniversary of the agreement, while the loan is outstanding, to convert an amount of up to $5.0 million of the principal amount of the outstanding loan into Common Stock (the "**Conversion Feature**") at a price per share equal to 120% of the stock purchase price set forth in the warrant. The Conversion Feature is subject to (i) the closing price of our Common Stock for each of the seven consecutive trading days immediately preceding the conversion being greater than or equal to the conversion price and (ii) the Common Stock issued in connection with any such conversion not exceeding 20% of the total trading volume of our Common Stock for the twenty-two consecutive trading days immediately prior to and including the effective date of such conversion.

Under the 2021 Avenue Loan, we agreed to affirmative and negative covenants to which we will remain subject upon maturity in the absence of prepayments. These covenants include 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. The financial covenant associated with the loan agreement includes maintaining minimum 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 (including any PIPE or follow-on offering) between May 1, 2021 and June 30, 2022, we shall no longer be subject to financial covenants. We are not in violation of the covenants. The agreement provides for events of default customary for loans of this type, including but not limited to non-payment, breaches or defaults in the performance of covenants, insolvency, and bankruptcy. The 2021 Avenue Loan is collateralized by substantially all of the Company's assets. 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 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. During the three and the six months ended June 30, 2021, we recorded interest expense of $0.2 million.

The loan consists of the following:

(in thousands)	**June 30, 2021**
Face value of the loan	$ 15,000
Unamortized debt discount associated with issuance date warrant fair value and financing costs	(1,859)
Total debt, net	$ 13,141

Following is a schedule of future payments, net of unamortized debt discounts, if Avenue does not convert up to $5.0 million of the loan into Common Stock between May 21, 2022 through May 21, 2024:

(in thousands)	**June 30, 2021**
2021 (remainder)	$ -
2022	3,000
2023	6,000
2024	6,000
2025	-
2026	-
Thereafter	-
Subtotal of future principal payments	$ 15,000
Unamortized debt discount associated with issuance date warrant fair value and financing costs	(1,859)
Total	$ 13,141

9. Preferred Stock Warrant Liability

Prior to the Reverse Recapitalization, we issued Series A Preferred Stock Warrants in 2013 pursuant to certain note purchase agreements. The warrants expire ten years from issuance. These warrants are exercisable at a fixed exercise price of $1.97, which is equal to the price per share of the Series A Preferred Stock. As of December 31, 2019, these warrants were exercisable into 1,608,670 shares of the Series A Preferred Stock.

Prior to the Reverse Recapitalization, on April 8, 2013, we issued ten-year warrants to purchase units of our most senior equity equal to 0.25% of our fully diluted equity at the time of exercise pursuant to certain note purchase agreements. As of December 31, 2019, these warrants were exercisable into 271,439 shares of our most senior equity, Series C Preferred Stock, at a fixed exercise price of $1.97 per share. On August 11, 2020, in connection with our issuance of Series D Preferred Stock, these warrants became exercisable into 320,441 shares of our most senior equity, Series D Preferred Stock, at a fixed exercise price of $1.97 per share.

Prior to the Reverse Recapitalization, we classified Preferred Stock warrants as a liability on the condensed consolidated balance sheets because the warrants are freestanding financial instruments that may have required us to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and is subsequently remeasured to fair value as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the Reverse Recapitalization (see Note 3), and pursuant to the Merger Agreement, all of the outstanding Clene Nanomedicine Preferred Stock was converted into Common Stock and the Clene Nanomedicine Preferred Stock warrants to purchase Clene Nanomedicine Preferred Stock were converted to warrants to purchase Common Stock (see Note 10). Upon conversion, we assessed the features of the warrants and determined that they qualify for classification as permanent equity upon the closing of the Reverse Recapitalization. Accordingly, we remeasured the warrants to fair value one final time upon the close of the Reverse Recapitalization, and recognized a loss of $14.6 million for the year ended December 31, 2020, within other income, (expense), net on the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the Reverse Recapitalization, the warrant liability was reclassified to additional paid-in capital (see Note 17).

As of June 30, 2021 and December 31, 2020, we do not have any Preferred Stock warrants outstanding.

We recognized a change in fair value of the outstanding warrants of $2.4 million during the three months ended June 30, 2020 and $2.3 million during the six months ended June 30, 2020 in the condensed consolidated statements of operations and comprehensive loss.

10. Common Stock Warrants

As of June 30, 2021, outstanding warrants to purchase shares of Common Stock consisted of the following:

Date Exercisable	Number of Shares Issuable	Exercise Price	Exercisable for	Classification	Expiration
June 2021	1,119,750(1)	$ 0.01	Common Stock	Equity	December 2021
December 2020	2,407,500(2)	$ 11.50	Common Stock	Equity	December 2025
December 2020	110,000(3)	$ 11.50	Common Stock	Equity	December 2025
December 2020	1,929,111(4)	$ 1.97	Common Stock	Equity	April 2023
May 2021	115,851(5)(6)	$ 8.63	Common Stock	Liability	May 2026
Total	5,682,212				

As of December 31, 2020, outstanding warrants to purchase shares of Common Stock consisted of the following:

Date Exercisable	Number of Shares Issuable	Exercise Price	Exercisable for	Classification	Expiration
June 2021	1,119,750(1)	$ 0.01	Common Stock	Equity	December 2021
December 2020	2,407,500(2)	$ 11.50	Common Stock	Equity	December 2025
December 2020	110,000(3)	$ 11.50	Common Stock	Equity	December 2025
December 2020	1,929,111(4)	$ 1.97	Common Stock	Equity	April 2023
Total	5,566,361				

(1) Consists of 1,119,750 shares of Common Stock underlying 1,119,750 PIPE Warrants issued on December 30, 2020, in connection with a private placement (see Note 18). A holder of the PIPE Warrants may not exercise the PIPE Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company's Common Stock outstanding immediately after giving effect to such exercise. As of June 30, 2021, and December 31, 2020, none of the warrants had been exercised.

(2) Consists of 2,407,500 shares of Common Stock underlying 4,815,000 warrants issued in connection with Tottenham's initial public offering. The Company may redeem the outstanding warrants, in whole and not in part, at a price of $0.01 per warrant if, and only if, the last sales price of the Company's Common Stock equals or exceeds $16.50 per share for any 20 trading days within a 30-trading day period ending three business days before the Company sends the notice of redemption. As of June 30, 2021, and December 31, 2020, none of the warrants had been exercised.

(3) Consists of 110,000 shares of Common Stock underlying 220,000 warrants issued as part of the Chardan Unit Purchase Option (see Note 3). As of June 30, 2021, and December 31, 2020, the Chardan Unit Purchase Option had not been exercised.

(4) Consists of 1,929,111 shares of Common Stock underlying 1,929,111 warrants originally issued by Clene Nanomedicine as Series A and Series D Preferred Stock Warrants (see Note 9). As of June 30, 2021, and December 31, 2020, none of the warrants had been exercised.

(5) Consists of 115,851 shares of Common Stock underlying 115,851 warrants issued pursuant to Tranche 1 of the 2021 Avenue Loan at an exercise price equal to the lower of (i) $8.63 (which is equal to the five-day VWAP per share, determined as of the end of trading on the last trading day prior to execution of the loan agreement), or (ii) the Next Round Price. (see Note 8). As of June 30, 2021, the warrant had not been exercised.

(6) Pursuant to the 2021 Avenue Loan, an additional 72,226 shares of Common Stock underlying 72,226 warrants are issuable pursuant to our draw of Tranche 2 between January 1, 2022 and June 30, 2022 (see Note 8). In accordance with ASC 815, we recognized these warrants at the inception of the 2021 Avenue Loan and classified them as a warrant liability (see Note 16). As of June 30, 2021, the warrant is not issued or outstanding.

11. Convertible Notes

2020 Convertible Notes

In February through July 2020, we issued convertible promissory notes (the "**2020 Convertible Notes**") in an aggregate principal amount of $6.1 million, bearing interest at an annual rate of 5%. The 2020 Convertible Notes were convertible at the earlier of (i) one year, at which point the notes would be convertible into Series C preferred shares at the Series C preferred share issuance price, and (ii) next equity financing of no less than $10.0 million, at which point the notes would be convertible into shares issued in the next equity financing at 90% of the per share issuance price of the next equity financing. The 2020 Convertible Notes contained embedded features that provide the lenders with multiple settlement alternatives. Certain of these settlement features provided the lenders with a right to a fixed number of our shares upon conversion of the notes. Other settlement features provided the lenders with the right or the obligation to receive cash or a variable number of shares upon the completion of a capital raising transaction, change of control, or default of the Company (the "**Redemption Features**"). The Redemption Features of the 2020 Convertible Notes met the requirements for separate accounting and were accounted for as a single derivative instrument (the "**2020 Derivative Instrument**"). Accordingly, the 2020 Derivative Instrument of $0.7 million was recorded at fair value at inception as redeemable convertible preferred stock derivative liability in the condensed consolidated balance sheets (see Note 12).

We recognized interest expense of $34 thousand, including amortization of debt discount of $0.1 million during the three months ended June 30, 2020, in connection with the 2020 Convertible Notes. We recognized interest expense of $42 thousand, including amortization of debt discount of $0.1 million during the six months ended June 30, 2020, in connection with the 2020 Convertible Notes.

On August 11, 2020, in connection with our issuance and sale of Series D Preferred Stock, all of the outstanding principal and accrued interest under the 2020 Convertible Notes, totaling $6.9 million, was automatically converted into 1,497,135 shares of Series D Preferred Stock at a price equal to 90% of $4.60 per share, the per share price paid in cash by investors in the Series D preferred stock financing. Upon the closing of the Reverse Recapitalization (see Note 3), and pursuant to the Merger Agreement, all outstanding Clene Nanomedicine Series D Preferred Stock was converted to Clene Inc. Common Stock.

We accounted for the conversion of the 2020 Convertible Notes as a debt extinguishment and recognized a loss on extinguishment of debt of $0.5 million within other income (expense), net in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020. As of the date of conversion, the unamortized discount on the 2020 Convertible Notes was $0.5 million. The loss on extinguishment was calculated as the difference between (i) the fair value of the 1,497,135 shares of Series D Preferred Stock issued to settle the 2020 Convertible Notes of $6.9 million and (ii) the carrying value of the 2020 Convertible Notes of $5.7 million, which includes the principal balance of the 2020 Convertible Notes of $6.1 million and accrued but unpaid interest of $0.1 million, net of the unamortized debt discount of $0.5 million, plus the then-current fair value of derivative liability associated with the 2020 Convertible Notes at the time of the extinguishment of $0.7 million.

Convertible Notes Payable

In May 2021, we entered into the 2021 Avenue Loan from which we granted to Avenue the right, in its discretion, but not the obligation, at any time from time to time from May 21, 2022 through May 21, 2024, while the loan is outstanding, to convert an amount of up to $5.0 million of the principal amount of the outstanding loan into shares of Common Stock at a price per share equal to 120% of the stock purchase price set forth in the warrant (see Note 8). The Conversion Feature is subject to (i) the closing price of our Common Stock for each of the seven consecutive trading days immediately preceding the conversion being greater than or equal to the conversion price and (ii) the Common Stock issued in connection with any such conversion not exceeding 20% of the total trading volume of our Common Stock for the twenty-two consecutive trading days immediately prior to and including the effective date of such conversion. The Conversion Feature did not meet the requirements for separate accounting and is not accounted for as a derivative instrument. As of June 30, 2021, the number of shares of Common Stock potentially issuable upon conversion was 482,703.

We classified $5.0 million of the 2021 Avenue Loan as convertible notes payable in the condensed consolidated balance sheets as of June 30, 2021, with unamortized debt discount and issuance costs of $0.6 million.

During the three and six months ended June 30, 2021, we recognized (i) total interest expense of $0.1 million; (ii) coupon interest expense of $0.1 million; and (iii) amortization of debt discount and issuance costs of $23 thousand in connection with the convertible notes payable. During the three and six months ended June 30, 2020, we did not recognize any interest expense or amortization in connection with the convertible notes payable. The effective interest rate was 17.93% for the three and six months ended June 30, 2021.

12. Derivative Instruments

Derivative instrument in connection with the 2020 Convertible Notes

One of the redemption features of the 2020 Convertible Notes met the requirements for separate accounting and was accounted for as a derivative instrument. The 2020 Derivative Instrument was recorded at fair value, which was $0.7 million at issuance. In August 2020, in connection with our issuance and sale of Series D Preferred Stock, all of the outstanding principal and accrued interest under the 2020 Convertible Notes was automatically converted into shares of Series D Preferred Stock and the derivative liability was extinguished. Prior to the extinguishment of derivative liability, the 2020 Derivative Instrument was marked to fair value and we recorded the change in the 2020 Derivative Instrument of ($29) thousand in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020 (see Note 11). For the three and six months ended June 30, 2020, we recorded the change in the 2020 Derivative Instrument of $10 thousand and $14 thousand, respectively, in the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the Reverse Recapitalization (see Note 3), and pursuant to the Merger Agreement, all outstanding Clene Nanomedicine Preferred Stock was converted to Clene Inc. Common Stock.

Derivative instruments in connection with the Contingent Earn-outs

The earn-out shares issued in connection with the Reverse Recapitalization met the requirements for separate accounting and are therefore accounted for as derivative instruments. Accordingly, upon the consummation of the Reverse Recapitalization, we recorded a liability in the condensed consolidated balance sheets and a debit to additional paid-in capital for the earn-out provision associated with the Initial Shareholders Contingent Earn-out and a debit to accumulated deficit for the earn-out provisions associated with the Clene Nanomedicine Contingent Earn-out. The contingent shares to be issued to the Clene Nanomedicine shareholders immediately prior to the Reverse Capitalization were treated as a deemed distribution. The Contingent Earn-outs were subsequently remeasured to fair value at each reporting date as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

Upon the closing of the Reverse Recapitalization, we recognized the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out liabilities at their fair value of $64.7 million and $7.4 million, respectively, in the condensed consolidated balance sheets. As of December 31, 2020, the carrying values of the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out were $52.1 million and $5.9 million, respectively. As of June 30, 2021, the carrying values of the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out were $69.0 million and $7.6 million, respectively. For the three months ended June 30, 2021, we recognized income of $8.6 million in change in fair value of the Clene Nanomedicine Contingent Earn-out and $1.2 million in change in fair value of the Initial Shareholders Contingent Earn-out as components of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. For the six months ended June 30, 2021, we recognized losses of $17.0 million in change in fair value of the Clene Nanomedicine Contingent Earn-out and $1.7 million in change in fair value of the Initial Shareholders Contingent Earn-out as components of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. To date, none of the milestones have been achieved.

Derivative instrument in connection with the 2021 Avenue Loan

The warrant issued pursuant to Tranche 1 of the 2021 Avenue Loan and the warrant issuable pursuant to the draw of Tranche 2 (see Note 8) met the requirements for separate accounting and is therefore accounted for as derivative instrument. The 2021 Avenue Loan has the following features: (i) prepayment provision, (ii) final payment provision, (iii) event of default redemption provision, and (iv) event of default interest provision. The provisions (i) to (iii) are related to the loan host and are not bifurcated pursuant to ASC 815. For the provision (iv), we have not experienced an event of default in the past and believe the probability of triggering one in the future is remote. Therefore, we determined the value of this feature to be de minimis on the remote probability of occurrence of a triggering event.

Upon the closing of the 2021 Avenue Loan, we recognized the warrant liability as a debt discount based on its fair value of $1.5 million. The debt discount is being amortized over the contractual term using the effective interest method. Our determination of the fair value of the warrant utilized the Black-Scholes option-pricing valuation model. Additionally, a Monte Carlo simulation was used to simulate the exercise price as an input in the Black-Scholes valuation model (see Note 10). For the three and six months ended June 30, 2021, we recognized income of $0.1 million in change in fair value of the warrant as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. To date, the warrant has not been exercised.

13. Commitments and Contingencies

Litigation

From time to time, we may have certain contingent 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 pending legal matters or claims.

14. Income Taxes

We recorded income tax benefits of $0.1 million and $0.1 million for the net operating losses incurred for the three and six months ended June 30, 2021. We have not recorded income tax benefits for the net operating losses incurred during the three and six months ended June 30, 2020. We have not recorded income tax benefits for research and development tax credits and other deferred tax assets generated, due to its uncertainty of realizing a benefit from those items.

The components of income (loss) before income taxes for the three and six months ended June 30, 2021 and 2020 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
United States	$ (2,574)	(5,968)	(41,295)	(9,354)
Foreign	(849)	149	(1,956)	(406)
Total loss before income taxes	$ (3,423)	$ (5,819)	$ (43,251)	$ (9,760)

The Company is subject to taxation in the United States, Australia, and various state jurisdictions. The Company computes its 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 the Company's U.S. net operating losses and other deferred tax assets.

15. Stock-Based Compensation

2020 Stock Plan

In December 2020, in connection with the Reverse Recapitalization, the Company's Board of Directors approved the 2020 Stock Plan (the "**2020 Stock Plan**") and reserved 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. The 2020 Stock Plan became effective immediately upon the closing of the Reverse Recapitalization. The maximum number of shares of Common Stock that may be issued pursuant to the exercise of incentive stock options under the 2020 Stock Plan is 12,000,000. Selected employees, officers, directors, and consultants are eligible to participate in the traditional stock option grants, stock appreciation rights, restricted stock awards, RSUs, other stock awards, and performance awards under the 2020 Stock Plan. The purpose of this 2020 Stock Plan is to enable us to offer competitive equity compensation packages in order to attract and retain the talent necessary for the combined company.

The 2020 Stock Plan is administered by the Company's Board of Directors. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the Company's Board of Directors, except that the exercise price per share of options may not be less than 100% of the fair market value of the Common Stock on the date of grant. Stock options awarded under the 2020 Stock Plan expire ten years after the grant date, unless the Company's Board of Directors sets a shorter term. Stock options and restricted stock granted to employees, officers, members of the Company's Board of Directors, and consultants generally vest over a four-year period. If an option or other award granted under the 2020 Stock Plan expires, terminates, or is cancelled, the unissued shares subject to that option or award shall again be available under the 2020 Stock Plan. If shares awarded pursuant to the 2020 Stock Plan are forfeited to or repurchased at original cost by the Company, the number of shares forfeited or repurchased at original cost shall again be available under the 2020 Stock Plan.

As of June 30, 2021, the Company's Board of Directors granted 3,806,257 RSUs and stock options under the 2020 Stock Plan. As of June 30, 2021, 8,193,743 shares remained available for future grant.

As of December 31, 2020, the Company's Board of Directors granted 1,507,062 RSUs under the 2020 Stock Plan. As of December 31, 2020, 10,492,938 shares remained available for future grant.

2014 Stock Plan

Following the closing of the Reverse Recapitalization, the 2014 Stock Plan is administered by the Company's Board of Directors. Stock options awarded under the 2014 Stock Plan expire ten years after the grant date. Stock options and restricted stock granted to employees, officers, members of the Company's Board of Directors, and consultants typically vest over a four-year period.

As a result of the Reverse Recapitalization (see Note 3), stock options outstanding under the 2014 Stock Plan of 53,286,115 were converted into 7,032,591 of stock options of the Company based on the Exchange Ratio determined in accordance with the terms of the Merger Agreement. The exchange of Clene Nanomedicine's stock options for Clene Inc. stock options was treated as a modification of the awards. The modification of the stock options did not result in a material incremental compensation expense to be recognized at the closing of the Reverse Recapitalization.

During the year ended December 31, 2020, the Company's Board of Directors granted stock options for 270,555 shares under the 2014 Stock Plan. Effective as of the closing of the Reverse Recapitalization on December 30, 2020, no additional awards may be made under the 2014 Stock Plan and as a result, (i) any shares in respect of stock options that are expired or terminated under the 2014 Stock Plan without having been fully exercised will not be available for future awards; (ii) any shares in respect of restricted stock that are forfeited to, or otherwise repurchased by the Company, will not be available for future awards; and (iii) any shares of Common Stock that are tendered to the Company by a participant to exercise an award will not be available for future awards.

Stock-based compensation expense for the three months ended June 30, 2021 and 2020 was approximately $4.2 million and $0.2 million, respectively, and approximately $7.5 million and $0.3 million for the six months ended June 30, 2021 and 2020, respectively. Stock-based compensation is recorded in research and development and general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Research and development	1,608	130	3,003	230
General and administrative	$ 2,647	44	4,517	115
Total stock-based compensation	$ 4,255	$ 174	$ 7,520	$ 345

Stock Options

The following sets forth the outstanding stock options and related activity for the six months ended June 30, 2021 (in thousands, except share and per share data):

Equity	**Number of Options**	**Original Weighted Average Exercise Price Per Share**	**Weighted Average Exercise Price Per Share**	**Weighted Average Remaining Term (Years)**	**Intrinsic Value**
Outstanding - December 31, 2020	7,032,591	$ 0.13	$ 0.97	5.34	$ 62,462
Granted	2,323,442	8.887	8.87	9.83	-
Exercised	(172,891)	0.62	0.62	-	1,836
Forfeited	(54,579)	8.26	8.26	-	-
Outstanding - June 30, 2021	9,128,563	$ 2.94	$ 2.94	6.09	$ 75,725
Options vested and exercisable - June 30, 2021	6,012,913	$ 0.70	$ 0.70	4.55	$ 63,381
Stock options vested and expected to vest - June 30, 2021	9,128,563	$ 2.94	$ 2.94	6.09	$ 75,725

As of June 30, 2021 and December 31, 2020, we had approximately $15.2 million and $2.4 million of unrecognized stock-based compensation costs related to non-vested stock options which is expected to be recognized over a weighted-average period of 2.14 and 2.04 years, respectively.

Prior to the consummation of the Reverse Recapitalization, the exercise price of the stock options granted was based on the fair market value of the common shares of the Company as of the grant date as determined by the Board of Directors, with input from management. The Board of Directors determined the fair value of the common stock at the time of grant of the options by considering a number of objective and subjective factors, including third-party valuation reports, valuations of comparable companies, sales of redeemable convertible Preferred Stock, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of the Company's capital stock, and general and industry-specific economic outlook.

Stock options are valued using the Black-Scholes valuation model. Since we have limited trading history of our Common Stock, the expected volatility is derived from the average historical stock volatilities of several unrelated public companies within our industry that we consider to be comparable to its own business 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 at the time of the grant. The expected dividend is assumed to be zero as we have never paid dividends and have no current plans to do so. The expected term represents the period that stock-based awards are expected to be outstanding. For option grants that are considered to be "plain vanilla," we determine the expected term using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For other option grants, we estimate the expected term using historical data on employee exercises and post-vesting employment termination behavior taking into account the contractual life of the award.

During the six months ended June 30, 2021, we granted stock options for 2,323,442 shares under the 2020 Stock Plan. The assumptions used to calculate the value of the stock option awards granted for the six months ended June 30, 2021 are presented as follows:

	Six months ended June 30, 2021	
Expected stock price volatility	84.8% - 87.7	%
Risk-free interest rate	0.59% - 1.90	%
Expected dividend yield	0.00	%
Expected term	6.00 years	

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2021 was $6.44.

Restricted Stock Units

On December 30, 2020, we granted the following shares of restricted stock units under the 2020 Stock Plan:

- 370,101 shares to various employees and non-employee directors, which vest on various dates between June 30, 2021 and January 15, 2022, subject to the employee's continuous employment through such vesting date. The RSUs convert to shares of Common Stock on a one-for-one basis upon vesting. The award represents 5% of the converted stock options under 2014 Stock Plan as a result of the Reverse Recapitalization and complements the 5% closing payment shares held in escrow for Clene Nanomedicine common shareholders (see Note 3). The grant-date fair value of these awards was $4.0 million based on the closing price of CLNN shares listed on Nasdaq of $10.82 per share on December 30, 2020, the date of the Reverse Recapitalization. As of June 30, 2021, there were 21,989 shares of Common Stock issued upon the vesting of RSUs. As of December 31, 2020 no shares were vested.

- 454,781 shares to various employees and non-employee directors, which were eligible to vest based on certain market conditions, subject to the employee's continuous employment through such vesting date. The award complements the Milestone 1 earn-out share entitlement of Clene Nanomedicine shareholders and vests based on the same market condition (see Note 3). The grant-date fair value of these awards, using a Monte Carlo simulation, was $4.3 million. Based on the outcome of the market condition as of the June 30, 2021 and December 31, 2020 measurement dates, no shares were vested.

- 341,090 shares to various employees and non-employee directors, which were eligible to vest based on certain market conditions, subject to the employee's continuous employment through such vesting date. The award complements the Milestone 2 earn-out share entitlement of Clene Nanomedicine. shareholders and vests based on the same market condition (see Note 3). The grant-date fair value of these awards, using a Monte Carlo simulation, was $3.5 million. Based on the outcome of the market condition as of the June 30, 2021 and December 31, 2020 measurement dates, no shares were vested.

- 341,090 shares to various employees and non-employee directors, which were eligible to vest based on certain performance conditions tied to the completion of the COVID-19 coronavirus treatment study, subject to the employee's continuous employment through such vesting date. The award complements the Milestone 3 earn-out share entitlement of Clene Nanomedicine shareholders and vests based on the same performance condition (see Note 3). The grant-date fair value of these awards was $3.7 million, based on the closing price of CLNN shares listed on Nasdaq of $10.82 per shares on December 30, 2020, the date of the Reverse Recapitalization. We did not recognize compensation expense because the occurrence of achieving this milestone was not probable. As of the June 30, 2021 and December 31, 2020 measurement dates, no shares were vested.

The following table summarizes the RSU activity during the six months ended June 30, 2021:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Outstanding and unvested balance as of December 31, 2020	1,507,062	$ 10.30
Converted to shares of Common Stock upon vesting	(21,989)	10.82
Forfeited	(2,258)	10.82
Outstanding and unvested balance as of June 30, 2021	1,482,815	$ 10.30

The assumptions used to calculate the value of the RSUs granted in 2020 in the Monte Carlo valuation model include projected stock price, volatility, and risk-free rate based on the achievement of certain stock price milestones. Our significant unobservable inputs as of December 31, 2020 were as follows: (i) 85% of expected stock price volatility, (ii) risk-free interest rate of 0.4%, and (iii) expected term of five years. The weighted average grant-date fair value of RSUs granted as of December 31, 2020 was $10.3034.

The stock-based compensation expense associated with the RSUs was $3.0 million and $6.0 million for the three and six months ended June 30, 2021. As of June 30, 2021 and December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was $5.4 million and $15.5 million, which is expected to be recognized over a weighted average period of less than 1 month and 6 months, respectively. We did not issue any RSUs during the six months ended June 30, 2020.

16. Fair Value

Cash is 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. The 2021 Avenue Loan is carried at amortized cost, which approximates fair value as its effective interest rate approximates current market rates.

Liabilities with Fair Value Measurements on a Recurring Basis

The following tables present our fair value hierarchy for liabilities measured at fair value on a recurring basis as of June 30, 2021 and December 31, 2020:

	Fair Value Measurements on a Recurring Basis June 30, 2021			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Notes payable	$ 1,617	$ -	$ -	$ 1,617
Warrant liability	-	-	1,324	1,324
Clene Nanomedicine contingent earn-out	-	-	69,023	69,023
Initial Shareholders contingent earn-out	-	-	7,635	7,635

	Fair Value Measurements on a Recurring Basis December 31, 2020			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Notes payable	$ 1,296	$ -	$ -	$ 1,296
Clene Nanomedicine contingent earn-out	-	-	52,053	52,053
Initial Shareholders contingent earn-out	-	-	5,906	5,906

There were no transfers between levels in the fair value hierarchy as of June 30, 2021 and December 30, 2020.

Valuation of Notes Payable

The carrying value of the notes payable includes certain notes remeasured at fair value on a recurring basis in the balance sheet as of June 30, 2021 and December 31, 2020. In order to value the note, we consider the amount of simple interest expense that would be due and the value of our Common Stock.

As of June 30, 2021, the fair value of our notes payable is determined based on the closing price of $11.24 per share as reported by Nasdaq.

As of December 31, 2020, the fair value of our notes payable is determined based on the closing price of $9.01 per share as reported by Nasdaq.

Valuation of Warrants to Purchase Preferred Stock

Our Preferred Stock warrant liabilities contain unobservable inputs that reflect our own assumptions. Accordingly, the Preferred Stock warrant liabilities were measured at fair value on a recurring basis using unobservable inputs. Prior to the extinguishment of the Preferred Stock warrant liabilities on December 30, 2020, the Preferred Stock warrant liability was valued using a Black-Scholes valuation model.

The Board of Directors determines the fair value of the Preferred Stock by considering a number of objective and subjective factors, including third-party valuations, valuations of comparable companies, sales of redeemable convertible Preferred Stock, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of our capital stock, and general and industry-specific economic outlook. We estimated the volatility of our Preferred Stock based on comparable peer companies' historical volatility. The risk-free interest rate for periods within the contractual life of the warrants is based on the U.S. Treasury yield curve in effect at the valuation date. We have no plans to declare any future dividends. The determination of the fair value of the Preferred Stock warrant liability could change in future periods based upon changes in the value of our Preferred Stock and other assumptions as presented above. We record any such change in fair value to the change in fair value of Preferred Stock warrant liability expense line in the condensed consolidated statements of operations and comprehensive loss.

Upon the closing of the Reverse Recapitalization (see Note 3), all of the outstanding Clene Nanomedicine Preferred Stock was converted to Clene Inc. Common Stock and the Clene Nanomedicine Preferred Stock warrants were converted to warrants for the purchase of Clene Inc. Common Stock. Accordingly, the Preferred Stock warrant liabilities were extinguished in connection with the conversion of Clene Nanomedicine Preferred Stock on December 30, 2020 (see Note 9).

Valuation of the Warrant Liability

Pursuant to the 2021 Avenue Loan, we issued to Avenue a warrant to purchase 115,851 shares of Common Stock pursuant to Tranche 1 of the 2021 Avenue Loan. In accordance with ASC 815, we recognized an additional warrant to purchase 72,226 shares of Common Stock that will be issued pursuant to the draw of Tranche 2 of the 2021 Avenue Loan (see Note 10). The warrants were recorded at fair value at the closing of the 2021 Avenue Loan on May 21, 2021, and will be remeasured at each reporting period.

The estimated fair value of the warrant liability was determined using a Black-Scholes valuation model, with a Monte Carlo analysis performed in order to simulate the Next Round Price as an input in the Black-Scholes valuation model. The carrying amount of the liability may fluctuate significantly and actual amounts may be materially different from the liabilities' estimated value. As of June 30, 2021, the warrant was revalued using a similar Black-Scholes valuation model. The unobservable inputs to the model were as follows:

Black-Scholes Valuation Model

	June 30, 2021	December 31, 2020
Expected stock price volatility	90.00%	N/A
Risk-free interest rate	0.80%	N/A
Expected dividend yield	0.00%	N/A
Expected term	4.89 years	N/A

Monte Carlo Simulation

	June 30, 2021	December 31, 2020
Expected stock price volatility	60.00 – 75.00%	N/A
Risk-free interest rate	0.05 – 0.07%	N/A
Expected dividend yield	0.00%	N/A
Expected term	0.25 years	N/A

Valuation of the Contingent Earn-outs

Pursuant to the Merger Agreement, Clene Nanomedicine's common shareholders immediately prior to the Reverse Recapitalization and Initial Shareholders of Tottenham were entitled to receive additional shares of up to 8,333,333 shares and 750,000 shares of Common Stock, respectively, upon us achieving certain milestones (see Note 3). Upon the consummation of the Reverse Recapitalization, Clene Nanomedicine and the Initial Shareholders are entitled to receive up to 8,346,185 additional shares as a result of the exercise of the stock options in November 2020, and 750,000 shares of Common Stock. The Contingent Earn-outs were recorded at fair value on the closing of the Reverse Recapitalization on December 30, 2020 and will be remeasured at each reporting period. As of June 30, 2021 and December 31, 2020, no milestone has been achieved.

The estimated fair value of the initial Contingent Earn-outs was determined using a Monte Carlo analysis 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. As of June 30, 2021 and December 31, 2020, the Contingent Earn-outs were revalued using a similar Monte Carlo analysis. The unobservable inputs to the models were as follows:

	June 30, 2021	December 31, 2020
Expected stock price volatility	90.00%	85.00%
Risk-free interest rate	0.80%	0.40%
Expected dividend yield	0.00%	0.00%
Expected term	4.50 years	5.00 years

The following is a summary of changes in the fair value of our financial liabilities related to the notes payable, the derivative instrument, the Preferred Stock warrants, the warrant liability, and the Contingent Earn-outs measured at fair value for the six months ended June 30, 2021 and 2020:

(in thousands)	Notes Payable	Clene Nanomedicine Contingent Earn-out	Initial Shareholders Contingent Earn-out	Warrant Liability
Balance - December 31, 2020	$ 1,296	$ 52,053	$ 5,906	$ -
Initial fair value of instrument	-	-	-	1,457
Change in fair value	321	16,970	1,729	(133)
Balance - June 30, 2021	$ 1,617	$ 69,023	$ 7,635	$ 1,324

(in thousands)	Notes Payable	Derivative Instrument	Preferred Stock Warrants
Balance - December 31, 2019	$ 640	$ -	$ 3,213
Issuance of convertible promissory notes	-	374	-
Change in fair value	24	(14)	2,307
Balance - June 30, 2020	$ 664	$ 360	$ 5,520

17. Redeemable Convertible Preferred Stock

In connection with the closing of the Reverse Recapitalization, the Preferred Stock converted into 36,893,894 shares of Common Stock on a 1:0.1389 basis (see Note 3). As of June 30, 2021 and December 31, 2020, there were no Preferred Stock outstanding.

The redeemable convertible preferred stock is described in Note 17, *Redeemable Convertible Preferred Stock* in Part II, Item 8 of our 2020 Annual Report on Form 10-K for the year ended December 31, 2020 ("**2020 Annual Report**") which was filed with the SEC on March 29, 2021. There have been no changes since our 2020 Annual Report.

18. Common Stock

As of June 30, 2021 and December 31, 2020, our certificate of incorporation, as amended and restated, authorized us to issue 150,000,000 and 100,000,000 shares of Common Stock, respectively, par value $0.0001 per share and 1,000,000 shares of Preferred Stock, par value $0.0001 per share. At our 2021 Annual Meeting of Stockholders on May 18, 2021, our stockholders approved an amendment to the Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock from 100,000,000 to 150,000,000.

Our common shareholders are entitled to one vote per share and to notice of any shareholders' 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 Shares have been paid or set aside for payment to the holders of Preferred Stock. Common Stock is not redeemable at the option of the holder.

On the closing of the Reverse Recapitalization, the total outstanding 2,303,495 Tottenham ordinary shares held by the Initial Shareholders and public shareholders were converted into the same number of Common Stock (see Note 3).

On the closing of the Reverse Recapitalization, 644,164 shares of Common Stock were issued to LifeSci as financial advisor to the Reverse Recapitalization (see Note 3).

Prior to the completion of the Reverse Recapitalization on December 30, 2020, the Company entered into a subscription agreement on December 28, 2020, with various investors. Pursuant to the subscription agreements, the Company issued 2,239,500 shares of Common Stock (the "**PIPE Shares**") at a price of $10.00 per share with net proceeds of $22.2 million. The purpose of the PIPE was to fund general corporate expenses. In addition, investors in the PIPE offering also received warrants to purchase a number of shares equal to one-half (1/2) of the number of PIPE Shares, totaling 1,119,750 shares of Common Stock, at an exercise price of $0.01 per share for each of the PIPE Shares (the "**PIPE Warrants**"), subject to a 180-day holding period (see Note 10).

On May 21, 2021, the Company entered into subscription agreements with various investors. Pursuant to the subscription agreements, the Company issued 960,540 shares of Common Stock at a price of $9.63 per share with net proceeds of $9.3 million. The closing of the private placement occurred substantially concurrently with, and was conditioned upon, the closing of a loan agreement with Avenue (see Note 8). The purpose of the private placement was to fund the expansion of manufacturing capabilities in the state of Maryland and to fund general corporate expenses.

As of June 30, 2021 and December 31, 2020, our common shares issued and outstanding were 60,681,591 and 59,526,171, respectively. As of June 30, 2021 and December 31, 2020, there were no preferred shares issued and outstanding (see Note 17).

19. Net Loss Per Share Attributable to Common Shareholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common shareholders (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Numerator:				
Net loss attributable to common shareholders	$ (3,351)	$ (5,819)	$ (43,107)	$ (9,760)
Denominator:				
Weighted average shares outstanding	61,165,018	17,357,505	60,919,340	17,357,505
Net loss per share attributable to common shareholders, basic and diluted	$ (0.05)	$ (0.34)	$ (0.71)	$ (0.56)

Included within weighted average common shares outstanding are 1,119,750 common shares issuable upon the exercise of the PIPE Warrants as the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common shareholders.

We have not considered the effect of the Chardan Unit Purchase Option that would convert to 242,000 shares of Common Stock and warrants to purchase 110,000 shares of Common Stock, in the calculation of diluted loss per share, since the conversion of the Chardan Unit Purchase Option and the exercise of the Chardan Unit Purchase Option Warrants into Common Stock would be anti-dilutive (see Notes 3 and 10).

The following shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common shareholders for the periods presented because including them would have been antidilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Series C redeemable convertible preferred stock	-	7,264,519		7,264,519
Series B redeemable convertible preferred stock	-	4,168,815		4,168,815
Series A redeemable convertible preferred stock	-	16,066,503		16,066,503
Series C redeemable convertible preferred stock warrants	-	271,439		271,439
Series A redeemable convertible preferred stock warrants	-	1,608,670		1,608,670
Convertible notes payable	482,703	-	482,703	-
Common stock warrants (see Note 10)	4,452,462	-	4,452,462	-
Options to purchase common stock	9,128,563	7,249,906	9,128,563	7,249,906
Unvested restricted stock units	1,482,815	-	1,482,815	-
Chardan Unit Purchase Option to purchase common stock (see Note 3)	242,000	-	242,000	-
Chardan Unit Purchase Option Warrants (see Notes 3 and 10)	110,000	-	110,000	-
Clene Nanomedicine contingent earn-out shares (see Note 3 and 12)	8,346,185	-	8,346,185	-
Initial Shareholders contingent earn-out shares (see Note 3 and 12)	750,000	-	750,000	-
Total	24,994,728	36,629,852	24,994,728	36,629,852

20. Related Party Transactions

For the three and six months ended June 30, 2020, we incurred $0.1 million of expenses for compensation for consulting services provided by a member of the Board of Directors. These expenses were not paid in their entirety and as of June 30, 2020, the outstanding balance of $0.1 million was recorded in accounts payable. As of June 30, 2021 and December 30, 2020, there was no outstanding balance due to this related party.

License and Supply Agreements

In August 2018, in conjunction with an investment made in our Series C Preferred Stock and Series C Preferred Stock Warrants by 4Life Research, LLC, an investor, we entered into a supply agreement with the investor. Under the terms of this agreement, we granted the investor an exclusive license to pursue development of dietary supplements using certain of our intellectual property ("**IP**"). The exclusive rights to the IP is for a term of five years from the commencement of sales of licensed product by the investor, with a deemed commencement date of January 1, 2023 if sales have not yet commenced, and is subject to annual minimum sales. The agreement may be renewed for additional five-year terms. If the investor fails to meet the annual minimum sales requirements, the investor may pay an additional fee to maintain exclusivity or have the investor's license converted to non-exclusive rights. As part of this agreement, we will provide non-pharmaceutical product to the investor for development efforts and potential future production, and the investor is to pay royalties of 3% of incremental sales, as defined in the agreement.

For the three and six months ended June 30, 2021, we sold $0.1 million and $0.3 million of product, respectively under this agreement. We did not sell any products outside of this agreement. For the three and six months ended June 30, 2021, the investor has made commercial sales of their products under the agreement which we recognized as royalty revenues of $0.1 million and $0.1 million, respectively.

For the six months ended June 30, 2020, we sold $0.1 million of product under this agreement, as well as $2 thousand of product not under this agreement, and received $0.1 million in advance to be applied against future sales of product under this agreement. We recorded this advanced amount as deferred revenue as of June 30, 2020, and we fulfilled the performance obligations to release the deferred revenue in the second half of 2021 as the investor purchased product. The investor did not make sales of their products under the agreement, and as such we did not recognize any royalty revenues for the six months ended June 30, 2020. For the three months ended June 30, 2020, we did not sell any product under this agreement, and there were no balances outstanding due to or from the investor.

21. Geographic and Segment Information

Geographic Information

Our long-lived assets, which were composed of property and equipment, net by location was as follows:

(in thousands)	As of June 30, 2021	As of December 31, 2020
United States	$ 4,041	$ 3,997
Australia	102	228
Total property and equipment, net	$ 4,143	$ 4,225

Segment Information

The operating results of the Drugs and Supplements segments for the three and six months ended June 30, 2021 and 2020 were as follows:

	For the Three Months ended June 30, 2021			**For the Six Months ended June 30, 2021**		
(in thousands)	**Drugs**	**Supplements**	**Total**	**Drugs**	**Supplements**	**Total**
Revenue from external customers	$ -	$ 201	$ 201	$ -	$ 414	$ 414
Loss from operations	$ (13,421)	$ (354)	$ (13,775)	$ (25,086)	$ (384)	$ (25,470)

	For the Three Months ended June 30, 2020			For the Six Months ended June 30, 2020		
(in thousands)	Drugs	Supplements	Total	Drugs	Supplements	Total
Revenue from external customers	$ -	$ 9	$ 9	$ -	$ 79	$ 79
Loss from operations	$ (4,570)	$ 9	$ (4,561)	$ (8,584)	$ 21	$ (8,563)

Our long-lived assets, which were composed of property and equipment, net by segment were as follows:

(in thousands)	As of June 30, 2021	As of December 31, 2020
Drugs	$ 3,923	$ 3,990
Supplements	220	235
Total property and equipment, net	$ 4,143	$ 4,225

22. Subsequent Events

On July 22, 2021, we filed a registration statement on Form S-1 (file number 333-258098) which was declared effective by the SEC on August 2, 2021 (see Note 1). In connection with the registration statement on Form S-1, we incurred an immaterial amount of certain offering costs which will be recognized as an expense within general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss during the three and nine months ended September 30, 2021.

Between July 1, 2021, and July 26, 2021, various investors exercised PIPE Warrants for 752,250 shares of Common Stock at an exercise price of $0.01 per share. The PIPE Warrants were issued prior to the completion of the Reverse Recapitalization on December 30, 2020, and were subject to a 180-day holding period which expired on June 28, 2021. We received cash proceeds of $8.0 thousand.

On July 15, 2021, Chardan exercised the Chardan Unit Purchase Option for 220,000 units, each unit consisting of one and one-tenth shares of Common Stock and one warrant to purchase one-half of one share of Common Stock at an exercise price of $11.50 per share. Chardan elected to perform a cashless or net exercise, which resulted in a net issuance of 54,083 shares of Common Stock and 49,166 warrants to purchase one-half of one share of Common Stock. The Chardan Unit Purchase Option was originally issued in connection with Tottenham's initial public offering in August 2018. We received no cash proceeds.

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 and other parts of this Quarterly Report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act"), as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The forward-looking statements include, but are not limited to, our expectations, hopes, beliefs, intentions, strategies, estimates, and assumptions concerning events and financial trends that may affect our future results of operations or financial condition. 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. These forward-looking statements are based on information available as of the date of this Quarterly Report and our management's current expectations, forecasts, and assumptions, and involve a number of judgments, risks, and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We disclaim any 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 specifically required under applicable securities laws.

As a result of a number of known and unknown risks and uncertainties, our actual results and the timing of events may differ materially from those expressed or implied by these forward-looking statements due to a number of factors, including those discussed in the section titled "Risk Factors" appearing elsewhere in this Quarterly Report.

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 the related notes appearing in Part I, Item I of this Quarterly Report on Form 10-Q and with our Annual Report on Form 10-K for the year ended December 31, 2020 (the "2020 Annual Report"), which was filed with the SEC on March 29, 2021, pursuant to Rule 424(b)(4) under the Securities Act, as amended.

Business Overview

We are a clinical-stage pharmaceutical company pioneering the discovery, development, and commercialization of novel, clean-surfaced nano ("**CSN**") therapeutics. CSN therapeutics are comprised of atoms of transition elements that, when assembled in nanocrystalline form, possess unusually high, unique catalytic activities not present in those same elements in bulk form. These nanocatalytic activities drive, support, and maintain beneficial metabolic and energetic intercellular 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 electrochemistry 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 Multiple Sclerosis ("**MS**"), Parkinson's Disease ("**PD**"), and Amyotrophic Lateral Sclerosis ("**ALS**"); and second, those related to the pandemic caused by COVID-19, a highly infectious viral respiratory disease with serious and sometimes fatal co-morbidities.

On December 30, 2020, Chelsea Worldwide Inc., our predecessor company, consummated the previously announced business combination (referred to as the "**Reverse Recapitalization**") pursuant to a merger agreement, dated as of September 1, 2020 (the "**Merger Agreement**"), by and among Clene Nanomedicine, Inc. ("**Clene Nanomedicine**"), Tottenham Acquisition I Limited ("**Tottenham**" or "**TOTA**"), the public entity prior to the Reverse Recapitalization, Chelsea Worldwide Inc., a Delaware corporation and wholly-owned subsidiary of Tottenham ("**PubCo**"), Creative Worldwide Inc., a Delaware corporation and wholly-owned subsidiary of PubCo ("**Merger Sub**"), and Fortis Advisors LLC, a Delaware limited liability company as the representative of our shareholders. Prior to the Reincorporation Merger discussed below, 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.

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**"); (ii) promptly following the Reincorporation Merger, Merger Sub was merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine being 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 Stock Exchange ("**Nasdaq**") under the symbol "CLNN." As a result of the Reverse Recapitalization, Clene Nanomedicine became a wholly-owned direct subsidiary of Clene Inc. For periods prior to the closing of the Reverse Recapitalization on December 30, 2020, the disclosure in *Management's Discussion and Analysis of Financial Condition and Results of Operations* has been updated to give effect to the Reverse Recapitalization.

We filed a registration statement on Form S-1 to register 4,541,481 shares of Common Stock underlying outstanding warrants that we had previously issued, which the SEC declared to be effective on April 19, 2021 (file number 333-253173). We will receive aggregate gross proceeds of $30.7 million if all of these warrants are exercised. In conjunction with the preparation of the registration statement on Form S-1, we incurred offering costs of $0 and $27 thousand for the three and six months ended June 30, 2021, which were recognized as an expense within general and administrative expenses in the condensed consolidated statement of operations. As of June 30, 2021, the Company did not receive any proceeds from the exercise of Tottenham warrants at an offering price per share of $11.50, Clene Nanomedicine warrants at an offering price per share of $1.97, and PIPE Warrants at an offering price per share of $0.01.

On May 21, 2021, we obtained a loan from Avenue Venture Opportunities Funds, L.P. ("**Avenue**") of $15.0 million with potential additional funding of $15.0 million and obtained from various new and existing investors $9.3 million of proceeds from a private placement of Common Stock. The loan with Avenue is associated with a warrant and a conversion right (see Note 8 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report).

We currently have no drugs approved by the US Food and Drug Administration 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 began supplying low-dose dietary supplements to 4Life Research, LLC, one of our shareholders, and had minimal direct sales of our rMetx™ ZnAg Immune Boost dietary supplement product. Our total loss from operations was $13.8 million and $25.5 million for the three and six months ended June 30, 2021. Our total loss from operations was $4.6 million and $8.6 million for the three and six months ended June 30, 2020. Substantially all of our losses from operations resulted from research and development expenses and administrative expenses. As of June 30, 2021 and December 31, 2020, we had an accumulated deficit of $196.7 million and $153.6 million, respectively.

We expect to continue investing in product development, sales and marketing, and customer support for our products and 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.

Impact of the COVID-19 Coronavirus 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 outbreak. The outbreak 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 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, 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 clinical research organizations ("**CROs**") may face disruptions that may affect our ability to initiate and complete preclinical studies, cause manufacturing disruptions, or create delays at clinical trial sites. The 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 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 and financial statements. While the COVID-19 pandemic has led to various research restrictions and paused 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 pandemic. We are not aware of any specific related event or circumstance that would require us to revise the estimates reflected in our financial statements. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, and financial condition, 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, we completed the previously announced Reverse Recapitalization (see *Business Overview* above).

At the closing of the Reverse Recapitalization, Clene Inc. acquired 100% of the issued and outstanding Clene Nanomedicine common stock, in exchange for 54,339,012 shares of Clene Inc. Common Stock issued to the Clene Nanomedicine common shareholders, of which 2,716,958 shares of the Clene Inc. Common Stock are to be issued and held in escrow to satisfy any indemnification obligations incurred under the Merger Agreement.

At the closing of the Reverse Recapitalization, each stock option of Clene Nanomedicine common stock was cancelled and the holders thereof in exchange received 0.1320 newly issued stock options of our Common Stock, which is 95% of the exchange ratio determined in the Merger Agreement. Pursuant to the Merger Agreement, we issued 370,101 of restricted stock units ("**RSUs**") to the option holders which complements the 5% closing payment shares held in escrow for Clene Nanomedicine common shareholders discussed above. In addition, we issued 1,136,961 RSUs to option holders to complement the earn-out payments that would contingently be issued to certain current Clene Nanomedicine's shareholders upon the achievement of milestones. See *Earn-out Shares* for the milestones detail.

Immediately after giving effect to the Reverse Recapitalization and the PIPE offering discussed below, there were 59,526,171 shares of Common Stock issued and outstanding and warrants to purchase 5,566,361 shares of Common Stock issued and outstanding.

The transaction was accounted for as a "reverse recapitalization" and Tottenham was treated as the "acquired" company for accounting purposes. Accordingly, for accounting purposes, the Reverse Recapitalization was treated as the equivalent of Clene Nanomedicine issuing shares for the net assets of Tottenham, accompanied by a recapitalization. The net assets of Tottenham were recorded at historical costs, with no goodwill or other intangible assets recorded. Reported amounts from operations included herein prior to the Reverse Recapitalization are those of Clene Nanomedicine.

The PIPE Offerings

Prior to the completion of the Reverse Recapitalization on December 30, 2020, we entered into subscription agreements on December 28, 2020, with various investors (the "**PIPE**"). Pursuant to the subscription agreements, we issued 2,239,500 shares of Common Stock (the "**PIPE Shares**") at a price of $10.00 per share with net proceeds of $22.2 million. The purpose of the PIPE was to fund general corporate expenses. In addition, investors in the PIPE offering will also receive warrants to purchase a number of shares equal to one-half (1/2) of the number of PIPE Shares, for an aggregate total of 1,119,750 shares of Common Stock, at an exercise price of $0.01 per share (the "**PIPE Warrants**"), subject to a 180-day holding period.

On May 21, 2021, the Company entered into subscription agreements with various investors. Pursuant to the subscription agreements, the Company issued 960,540 shares of Common Stock at a price of $9.63 per share with net proceeds of $9.3 million. The closing of the private placement occurred substantially concurrently with, and was conditioned upon, the closing of a loan agreement with Avenue (see Note 8 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report). The purpose of the private placement was to fund the expansion of manufacturing capabilities in the state of Maryland and to fund general corporate expenses.

Key Factors Affecting Our Results of Operations

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

Earn-out Shares

In connection with the Reverse Recapitalization, certain of Clene Nanomedicine's current shareholders and Tottenham's former officers and directors and the Sponsor (collectively, the "**Initial Shareholders**") are entitled to receive earn-out payments (the "**Contingent Earn-outs**") based on achieving milestones discussed below. 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 loss for the three and six months ended June 30, 2021.

The Contingent Earn-out provision for Clene Nanomedicine's common shareholders (the "**Clene Nanomedicine Contingent Earn-out**") includes (i) Milestone 1 that is based on achieving a certain volume-weighted average price ("**VWAP**") of the shares of our Common Stock within three years after the closing of the Reverse Recapitalization or the change of control price equaling or exceeding a certain price if a change of control transaction occurs within the three years following the closing of the Reverse Recapitalization, (ii) Milestone 2 that is based on achieving a certain VWAP of the shares of our Common Stock within five years after the closing of the Reverse Recapitalization or the change of control price equaling or exceeding a certain price if a change of control transaction occurs within the five years following the closing of the Reverse Recapitalization, and (iii) Milestone 3 that is based on completing by December 30, 2021 a randomized placebo-controlled study for treatment of COVID-19 coronavirus.

The Contingent Earn-out provision for the Initial Shareholders (the "**Initial Shareholders Contingent Earn-out**") includes Milestone 1 and Milestone 2 listed above. Upon the consummation of the Reverse Recapitalization, Clene Nanomedicine and the Initial Shareholders are entitled to receive up to 8,346,185 and 750,000 shares of Common Stock, respectively.

The estimated fair values of the contingent consideration were determined using Monte Carlo simulations that simulated the future path of our Common Stock price over the earn-out periods. The assumptions utilized in the calculations are based on the achievement of certain stock price milestones including projected stock price, volatility, and risk-free rate. For potential payments related to a product development milestone, the fair value was determined based on our expectations of achieving such a milestone and the simulated estimated stock price on the expected date of achievement.

Contingent Earn-out payments involve certain assumptions requiring significant judgment and actual results may differ from assumed and estimated amounts.

Research and Development Expenses

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.

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, expenses incurred for payments to CROs, principal investigators and clinical trial sites, costs of materials to support our clinical trials and preclinical studies, costs associated with preclinical activities, share awards granted to our research and development personnel, and salaries for our expanding research and development personnel. 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.

Funding for Our 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 proceeds from the issuance of preferred stock, issuance of common stock upon exercise of common stock options, convertible promissory notes, issuances of notes payable, the consummation of the Reverse Recapitalization, and the consummation of PIPE offerings.

Since our inception and through the date of this Quarterly Report, we have funded our operations primarily with proceeds from the following sources:

- gross proceeds of $87.2 million from sales of our preferred stock and other equity financing;
- gross proceeds of $28.1 million from borrowings under convertible promissory notes;
- gross proceeds of $0.6 million through government lending;
- gross cash proceeds of $31.7 million from the Reverse Recapitalization and the December 2020 PIPE offering;
- gross cash proceeds of $0.6 million from a Program Paycheck Protection loan obtained through the U.S. Small Business Administration, which was forgiven in January 2021;
- gross cash proceeds of $9.3 million from the May 2021 PIPE offering; and
- gross cash proceeds of $15.0 million through the 2021 Avenue Loan.

We have also been awarded grants from various other organizations, including the National Multiple Sclerosis Society; FightMND, a not-for-profit registered charity in Australia; and the Michael J. Fox Foundation, who together have issued us grants totaling approximately $1.9 million. We also receive indirect financial support for one of the clinical studies in which we participate, the Healey ALS Platform Trial, administered by the Massachusetts General Hospital, which is conducting a study of our CNM-Au8 drug candidate along with other drugs in a platform trial, at significantly lower costs to us than we would otherwise incur if we were to conduct a comparably designed study on our own at reasonable market rates. In December 2019, we were awarded a grant from the U.S. Congressionally Directed Medical Research Program administered by the Department of Defense for $1.3 million, which as of June 17, 2021, we have determined not to accept. No amounts relating to this award were recognized in the financial statements of any period and therefore there will be no impact to our financial position or to the results of our operations or our cash flows for any period.

The net cash used in our operating activities was $17.7 million and $5.4 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had cash of $63.0 million. We expect that the cash on hand as of June 30, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date the condensed consolidated financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we may exhaust our available capital resources sooner than we anticipate. See *Liquidity and Capital Resources*. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug products and continue research and development of our preclinical drug products and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug products. As we continue to grow and expand, we will incur more expenses relating to regulatory compliance and sales and marketing personnel as we prepare to commence commercialization once we obtain regulatory approval of our drug products.

General and Administrative Expenses

Our general and administrative expenses consist primarily of staff costs, agency and consulting fees, utilities, rent and general office expenses, share grants, and RSUs grants. We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as we continue to rapidly advance the clinical programs of our drug products and expect to commercialize our products once we receive regulatory approval. These increases will likely include increased headcount, increased share compensation charges, expanded infrastructure, and increased insurance expenses. We also anticipate increasing legal, compliance, accounting, and investor and public relations expenses associated with being a public company.

Grants and Government Tax Incentives

We received grants issued by non-government entities related to income which have future related costs expected to be incurred and require us to comply with conditions attached to the grants. These non-government grants related to income are recognized in profit or loss as an offset to research and development expenses when funding has been received and related costs have been incurred. We received 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. We recognized $0.2 million of grant funding against research and development expenses for the three and six months ended June 30, 2021. We recognized $0.2 million and $0.4 million of grant funding against research and development expenses for the three and six months ended June 30, 2020. We recognized $0.4 million and $0.7 million of other income for the three and six months ended June 30, 2021 that we classified as Australia research and development credit. We did not recognize other income for the three and six months ended June 30, 2020.

Commercialization of Our Drug Candidates

Our business and results of operations depend on our ability to commercialize our drug candidates, if approved for marketing. Our pipeline is comprised of four drug candidates ranging from pre-clinical to late-stage clinical programs, including two drug candidates at the clinical stage or IND stage. Although we currently do not have any drug candidates approved for commercial sale and have not generated any revenue from drug product sales, we expect to commercialize one or more of our drug products in the coming years as they move toward the final stages of development. While we began selling our ZnAg Immune Boost product online in May 2020, we anticipate revenue generated from sales of this dietary supplement will be small compared to our operating expenses as well as the revenue we expect to generate from future sales of our drug candidates for which we are currently conducting clinical trials.

Components of Results of Operations

Comparison of the three months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020:

	Three Months ended June 30,	
	2021	**2020**
	(in thousands)	
Product revenue	$ 138	$ 9
Royalty revenue	63	-
Total revenue	201	9
Operating expenses:		
Cost of revenue	555	-
Research and development	6,472	3,554
General and administrative	6,949	1,016
Total operating expenses	13,976	4,570
Loss from operations	(13,775)	(4,561)
Other income (expenses):		
Interest expense	(26)	(190)
Gain on extinguishment of notes payable	-	-
Gain on termination of lease	-	51
Change in fair value of preferred stock warrant liability	-	(2,419)
Change in fair value of derivative liability	-	10
Change in fair value of Clene Nanomedicine contingent earn-out	8,640	-
Change in fair value of Initial Shareholders contingent earn-out	1,232	-
Change in fair value of common stock warrant liability	133	-
Australia research and development credit	375	1,268
Other income, net	(2)	22
Total other income (expense), net	10,352	(1,258)
Net loss before income taxes	(3,423)	(5,819)
Income tax benefit	72	-
Net loss	(3,351)	(5,819)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(61)	10
Total other comprehensive income (loss)	(61)	10
Comprehensive loss	$ (3,412)	$ (5,809)

Comparison of the six months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

	Six Months ended June 30,	
	2021	**2020**
	(in thousands)	
Product revenue	$ 337	$ 79
Royalty revenue	77	-
Total revenue	414	79
Operating expenses:		
Cost of revenue	798	58
Research and development	12,747	6,756
General and administrative	12,339	1,828
Total operating expenses	25,884	8,642
Loss from operations	(25,470)	(8,563)
Other income (expenses):		
Interest expense	(577)	(241)
Gain on extinguishment of notes payable	647	-
Gain on termination of lease	-	51
Change in fair value of preferred stock warrant liability	-	(2,307)
Change in fair value of derivative liability	-	14
Change in fair value of Clene Nanomedicine contingent earn-out	(16,970)	-
Change in fair value of Initial Shareholders contingent earn-out	(1,729)	-
Change in fair value of common stock warrant liability	133	-
Australia research and development credit	714	1,268
Other income, net	1	18
Total other income (expense), net	(17,781)	(1,197)
Net loss before income taxes	(43,251)	(9,760)
Income tax benefit	144	-
Net loss	(43,107)	(9,760)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(37)	16
Total other comprehensive income (loss)	(37)	16
Comprehensive loss	$ (43,144)	$ (9,744)

Revenue

We generated revenue of $0.2 million and $0.4 million for the three and six months ended June 30, 2021. Product revenue of $0.1 million and $0.3 million was recognized in our dietary supplement segment under a supply agreement with 4Life Research, LLC, a related party, for KHC46 and a low dose zinc-silver solution, two dietary (mineral) supplements that we began supplying during those periods.

We generated revenue of $9 thousand and $0.1 million for the three and six months ended June 30, 2020. All of our revenue was product revenue from our supply agreement with 4Life Research, LLC, a related party, for KHC46 and a low dose zinc-silver solution, two dietary (mineral) supplements that we began supplying during those periods.

We also generated minimal product revenue from sales of rMetx™ ZnAg Immune Boost during those periods. In addition, $0.1 million and $0.1 million of our revenue during the three and six months ended June 30, 2021 was paid to us by 4Life Research, LLC under an exclusive and royalty-bearing license agreement relating to the sales of KHC46. We did not generate royalty revenue during the three and six months ended June 30, 2020. For more details on the license agreement, see Note 20 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Operating Expenses

Cost of Sales

We incurred cost of sales of $0.6 million and $0.8 million for the three and six months ended June 30, 2021, relating to production and distribution costs for the sales of our KHC46 and low dose zinc-silver solution dietary supplement products.

We incurred insignificant cost of sales for the three and six months ended June 30, 2020, relating to production and distribution costs for the sales of our KHC46 and low dose zinc-silver solution dietary supplement products.

Research and Development Expenses

Research and development expenses were (i) $6.5 million and $3.6 million for the three months ended June 30, 2021 and 2020, respectively, and (ii) $12.7 million and $6.8 million for the six months ended June 30, 2021 and 2020, respectively. During these periods, substantially all of our research and development expenses were related to the development and clinical trials of our lead drug candidate, CNM-Au8. The increases for the three and six months ended June 30, 2021 and 2020 of $2.9 million, or 82.1% and $6.0 million, or 88.7%, respectively, were primarily due to the progression of our drug candidates through the clinical development process, including increased enrollment into the REPAIR-PD and the REPAIR-MS studies, and calendar payments due for our participation in the Healey-ALS Platform Trial. These efforts resulted in greater associated costs and manufacturing expenses in support of these trials. Also, during the three and six months ended June 30, 2021 and 2020, Research and Development expenses included $1.6 million and $3.0 million, respectively of share-based compensation expense related to stock options and RSUs.

Historically, substantially all of our research and development expenses relate to CNM-Au8, our lead asset. 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 studies, the costs of opening and monitoring clinical sites, CRO activity, and manufacturing expenses. We expect that our research and development expenses will increase in connection with our clinical development activities in the near term and in the future.

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 for employees engaged in research and development functions; clinical trial supplies; fees for clinical trial services; 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 Expenses

General and administrative expenses consist of employee salary and benefits; share-based compensation expenses; professional fees for legal, consulting, and audit services; fees for business development activities; facility expenses; travel expenses; rental fees; and other administrative expenses. We expect our general and administrative expenses to increase as we continue to grow and expand. General and administrative expenses were (i) $6.9 million and $1.0 million for the three months ended June 30, 2021 and 2020, respectively, and (ii) $12.3 million and $1.8 million for the six months ended June 30, 2021 and 2020, respectively. The increases for the three and six months ended June 30, 2021 and 2020 of $5.9 million or 584.0% and $10.5 million or 575.0%, respectively, were primarily due to (i) increased professional expenses, public company expenses, legal fees, accounting fees, tax fees, and director and officer insurance policies as a result of becoming a public company on December 30, 2020 to support our efforts to comply with SEC rules and regulations, and (ii) $2.6 million and $4.5 million of share-based compensation expense related to stock options and RSUs during the three and six months ended June 30, 2021.

Other Income (Expenses)

Other income (expenses) consists of interest expenses, interest income, gain on termination of leases, changes in fair value of preferred stock warrant liability, changes in fair value of derivative liability, changes in fair value of Clene Nanomedicine contingent earn-out, changes in fair value of Initial Shareholders contingent earn-out, changes in fair value of common stock warrant liability, a research and development credit received from the Australian government, foreign exchange gain (loss), gain (loss) on disposal of assets, and gain (loss) on extinguishment of notes payable. Other income (expenses), net for the three months ended June 30, 2021 and 2020 included the following:

(i) recognized interest expense of $26 thousand for the three months ended June 30, 2021, due to interest expense on the 2021 Avenue Loan of $0.2 million, partially offset by a decrease in the fair value of our notes payable. As of June 30, 2021, the fair value of our notes payable is determined based on the closing price of CLNN shares listed on Nasdaq of $11.24 per share.

(ii) recognized interest expense of $0.2 million for the three months ended June 30, 2020, due to an increase in the fair value of our notes payable and the interest expense associated with the Series D convertible notes.

(iii) recognized gain on termination of leases of $0.1 million due to the termination of an operating lease for office space for the three months ended June 30, 2020.

(iv) recognized expense of $2.4 million relating to the changes in fair value of preferred stock warrant liability for the three months ended June 30, 2020. There was no preferred stock warrant liability as a result of the Reverse Recapitalization on December 30, 2020. Upon the consummation of the Reverse Recapitalization, we determined that the warrants qualify for classification as permanent equity and we reclassified the resulting warrant liability to additional paid-in capital. No change in fair value of preferred stock warrant liability is recorded going forward.

(v) recognized income for the change in fair value of our Clene Nanomedicine contingent earn-out liability of $8.6 million for the three months ended June 30, 2021. The change in fair value was primarily a result of the decrease of the closing price of CLNN shares listed on Nasdaq to $11.24 per share on June 30, 2021 from $12.78 per share on March 31, 2021 when we remeasured the Clene Nanomedicine contingent earn-out liability at June 30, 2021. There was no Clene Nanomedicine contingent earn-out liability for the three months ended June 30, 2020.

(vi) recognized income for the change in fair value of our Initial Shareholders contingent earn-out liability of $1.2 million for the three months ended June 30, 2021. The change in fair value was primarily a result of the decrease of the closing price of CLNN shares listed on Nasdaq to $11.24 per share on June 30, 2021 from $12.78 per share on March 31, 2021 when we remeasured the Initial Shareholders contingent earn-out liability at June 30, 2021. There was no Initial Shareholders contingent earn-out liability for the three months ended June 30, 2020.

(vii) recognized income of $0.4 million and $1.3 million, respectively, relating to a research and development credit received from the Australian government. We recognized Australian research and development credit in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. The decrease in research and development credit is the result of decreased research and development activities during the three months ended June 30, 2021.

(viii) recognized the change in fair value of our Avenue warrant of $0.1 million for the three months ended June 30, 2021. The change in fair value was primarily a result of the decrease of the expected term to 4.89 years on June 30, 2021 from 5.0 years on May 21, 2021, partially offset by the increase of the closing price of CLNN shares listed on Nasdaq to $11.24 per share on June 30, 2021 from $9.63 per share on May 21, 2021 when we remeasured the Avenue warrant to fair value at June 30, 2021. There was no Avenue warrant for the three months ended June 30, 2020.

Other income (expenses), net for the six months ended June 30, 2021 and 2020 included the following:

(i) recognized interest expense of $0.6 million and $0.2 million, respectively, due to an increase in the fair value of our notes payable and the interest expense on the 2021 Avenue Loan of $0.2 million. As of June 30, 2021, the fair value of our notes payable is determined based on the closing price of CLNN shares listed on Nasdaq of $11.24 per share.

(ii) recognized gain on extinguishment of notes payable of $0.6 million, due to the forgiveness of the PPP Loan by the U.S. Small Business Administration.

(iii) recognized gain on termination of leases of $0.1 million due to the termination of an operating lease for office space for the six months ended June 30, 2020.

(iv) recognized expense of $2.3 million relating to the changes in fair value of preferred stock warrant liability for the six months ended June 30, 2020. There was no preferred stock warrant liability as a result of the Reverse Recapitalization on December 30, 2020. Upon the consummation of the Reverse Recapitalization, we determined that the warrants qualify for classification as permanent equity and we reclassified the resulting warrant liability to additional paid-in capital. No change in fair value of preferred stock warrant liability is recorded going forward.

(v) recognized expense for the change in fair value of our Clene Nanomedicine contingent earn-out liability of $17.0 million for the six months ended June 30, 2021. The change in fair value was primarily a result of the increase of the closing price of CLNN shares listed on Nasdaq to $11.24 per share on June 30, 2021 from $9.01 per share on December 31, 2020 when we remeasured the Clene Nanomedicine contingent earn-out liability at June 30, 2021. There was no Clene Nanomedicine contingent earn-out liability for the six months ended June 30, 2020.

(vi) recognized expense for the change in fair value of our Initial Shareholders contingent earn-out liability of $1.7 million for the six months ended June 30, 2021. The change in fair value was primarily a result of the increase of the closing price of CLNN shares listed on Nasdaq to $11.24 per share on June 30, 2021 from $9.01 per share on December 31, 2020 when we remeasured the Initial Shareholders contingent earn-out liability at June 30, 2021. There was no Initial Shareholders contingent earn-out liability for the six months ended June 30, 2020.

(vii) recognized income of $0.7 million and $1.3 million, respectively, relating to a research and development credit received from the Australian government. We recognized Australian research and development credit in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. The decrease in research and development credit is the result of decreased research and development activities in Clene Australia during the six months ended June 30, 2021.

(viii) recognized the change in fair value of our Avenue warrant of $0.1 million for the six months ended June 30, 2021. The change in fair value was primarily a result of the decrease of the expected term to 4.89 years on June 30, 2021 from 5.0 years on May 21, 2021, partially offset by the increase of the closing price of CLNN shares listed on Nasdaq to $11.24 per share on June 30, 2021 from $9.63 per share on May 21, 2021 when we remeasured the Avenue warrant fair value at June 30, 2021. There was no Avenue warrant for the three months ended June 30, 2020.

Comprehensive Loss

As a result of the foregoing, we incurred a comprehensive loss of (i) $3.4 million and $5.8 million for the three months ended June 30, 2021 and 2020, respectively, and (ii) $43.1 million and $9.7 million for the six months ended June 30, 2021 and 2020, respectively.

Taxation

United States

We are incorporated in Delaware in the U.S. and subject to statutory U.S. federal corporate income tax at a rate of 21% for the three and six months ended June 30, 2021 and 2020. We are also subject to state income tax in Utah and Maryland, at a rate of 4.95% and 8.25%, respectively, for the six months ended June 30, 2021 and 2020. As of June 30, 2021 and December 31, 2020, 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, was established in Australia on March 5, 2018 and is subject to corporate income tax at a rate of 25.0% and 27.5% for the three and six months ended June 30, 2021 and 2020, respectively. Clene Australia total income tax benefit was $0.1 million and $0.1 million for the three and six months ended June 30, 2021. During the three and six months ended June 30, 2020, Clene Australia had no taxable income and therefore, no provision for income taxes was required. We recorded $0.4 million and $0.7 million as other income during the three and six months ended June 30, 2021 for a refund of research and development credits pertaining to Clene Australia for the 2021 tax year. We recorded $1.3 million as other income during the three and six months ended June 30, 2020 for a refund of research and development credits pertaining to Clene Australia for the 2020 tax year.

Netherlands

Our wholly-owned subsidiary, Clene Netherlands B.V., was established in the Netherlands on April 21, 2021 and will be subject to corporate income tax at a rate of 15% up to €245,000 of taxable income and 25% for taxable income in excess of €245,000. As Clene Netherlands was established during this quarter with no current activities, it had no taxable income and therefore, no provision for income taxes was required.

JOBS Act

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use the extended transition period under the JOBS Act until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date on which we are deemed to be a "large accelerated filer," which would occur if the market value of our equity securities held by non-affiliates exceeds US$700 million as of the last business day of our most recently completed second fiscal quarter; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; or (4) the last day of the fiscal year ending after the fifth anniversary of Tottenham's initial public offering, or August 6, 2023.

We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for public companies.

Smaller Reporting Company Status

We are a Smaller Reporting Company as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until (1) the market value of our Common Stock held by non-affiliates exceeds $250 million as of the end of the second fiscal quarter and our annual revenues exceed $100 million during the previous fiscal year, or (2) the market value of our Common Stock held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter.

Liquidity and Capital Resources

Since inception, we have incurred annual net losses from our operations. Substantially all of our losses have resulted from the funding of our research and development programs and general and administrative expenses associated with our operations. We incurred net losses of $3.4 million and $43.1 million for the three and six months ended June 30, 2021. We incurred net losses of $5.8 million and $9.8 million for the three and six months ended June 30, 2020. Our loss from operations was $13.8 million and $25.5 million for the three and six months ended June 30, 2021. Our loss from operations was $4.6 million and $8.6 million for the three and six months ended June 30, 2020. We have financed our operations principally through proceeds from the sale of preferred stock, the sale of preferred stock warrants, the sale of convertible notes that have converted into shares of preferred stock, the sale of shares of common stock underlying outstanding warrants, and through the funds we raised from the consummation of the Reverse Recapitalization and the PIPE offering. During the six months ended June 30, 2021, we raised $9.3 million from a PIPE offering and obtained $15.0 million under the 2021 Avenue Loan. During the six months ended June 30, 2020, we raised an aggregate of $3.8 million, consisting of net proceeds from issuance of notes payable and convertible notes payable.

The net cash used in our operating activities was $17.7 million and $5.4 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had cash of $63.0 million. We expect that the cash on hand as of June 30, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date the condensed consolidated financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we may exhaust our available capital resources sooner than we anticipate. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug products and continue research and development of our preclinical drug products and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug products. As we continue to grow and expand, we will incur more expenses relating to regulatory compliance and sales and marketing personnel as we prepare to commence commercialization once we obtain regulatory approval of our drug products.

Our ability to continue as a going concern may require obtaining additional funding to finance operations. As part of our ongoing business plans, we will continue seeking funding through equity financing and may seek debt financing or other capital sources. We may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of our shareholders. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate research and development programs and commercialization efforts.

The following table provides information regarding our cash flows for relevant periods:

	Six Months ended June 30,	
(in thousands)	**2021**	**2020**
Net cash used in operating activities	$ (17,713)	$ (5,402)
Net cash used in investing activities	(420)	(194)
Net cash provided by (used in) financing activities	21,898	3,668
Effect of foreign exchange rate changes on cash	(33)	29
Net increase (decrease) in cash	3,732	(1,899)

Use of Funds

Our primary use of cash in all periods presented was to fund our research and development, regulatory and other clinical trial costs, and related supporting administration. Our prepaid expenses and other current assets, accounts payable, and accrued expense balances in all periods presented were affected by the timing of vendor invoicing and payments, and impacted the cash provided by, or used in, operations. We have no commitments for capital expenditures as of the end of the latest fiscal period.

Operating Activities

Net cash used in operating activities was $17.7 million of cash for the six months ended June 30, 2021, which resulted from a net loss of $43.1 million, adjusted for (i) non-cash items of $26.4 million, which primarily consisted of depreciation expense of $0.5 million, stock-based compensation expenses of $7.5 million, changes in fair value of the Clene Nanomedicine contingent earn-out of $17.0 million, changes in fair value of the Initial Shareholders contingent earn-out of $1.7 million, changes in fair value of the common stock warrant liability of $0.1 million, gain on extinguishment of debt of $0.6 million, and increase in interest accrued on notes payable of $0.4 million; and (ii) a net change in operating assets and liabilities of $1.0 million. The net change in operating assets and liabilities was primarily attributable to an decrease in inventory of $0.1 million; an increase in prepaid expenses and other current assets of $1.5 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 the decrease in CRO prepayments; $0.6 million increase in accounts payable and $0.1 million increase in accrued liabilities due to the timing of vendor invoicing and payments; $0.1 million decrease in deferred income tax; and $0.1 million decrease in payments of operating lease obligations.

Net cash used in operating activities was $5.4 million of cash for the six months ended June 30, 2020, which resulted from a net loss of $9.8 million, adjusted for (i) non-cash items of $3.3 million, which primarily consisted of depreciation expense of $0.5 million, stock-based compensation expenses of $0.4 million, changes in the fair value of preferred stock warrant liability of $2.3 million, and accretion of debt discount of $0.1 million; and (ii) a net change in operating assets and liabilities of $1.0 million. The net change in operating assets and liabilities was primarily attributable to a $1.0 million increase in accounts payable due to the timing of vendor invoicing and payments, $0.1 million decrease in accrued liabilities due to the timing of vendor invoicing and payments, $0.1 million increase in deferred revenue from related parties, and $0.1 million increase in deferred revenue from related parties.

Investing Activities

Net cash used in investing activities was $0.4 million and $0.2 million for the six months ended June 30, 2021 and 2020, respectively, which in each instance was related to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $21.9 million for the six months ended June 30, 2021, which primarily resulted from (i) proceeds from the May 2021 PIPE of $9.3 million, (ii) proceeds from the issuance of notes payable of $15.0 million, and (iii) proceeds from exercise of stock options of $0.1 million, partially offset by (i) payments of deferred transaction costs of $1.9 million, (ii) payments of debt issuance costs of $0.5 million, (iii) payments on our finance lease obligations of $0.1 million, and (iv) payments of notes payable of $5 thousand.

Net cash provided by financing activities was $3.7 million for the six months ended June 30, 2020, which primarily resulted from proceeds from the issuance of notes payable of $3.1 million and the issuance of notes payable of 0.7 million, partially offset by payments on our finance lease obligations of $0.1 million.

Debt Obligations

Maryland Loan

In February 2019, we entered into a loan agreement (the "**2019 MD Loan**") with the Department of Housing and Community Development, a principal department of the State of Maryland ("**Maryland**"). Pursuant to the 2019 MD Loan, Maryland agreed to provide a $0.5 million term loan. Amounts outstanding under the 2019 MD Loan bear simple interest at an annual rate of 8.00%. Under the 2019 MD Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include 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 Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on February 22, 2034. The 2019 MD Loan establishes "Phantom Shares," based on 119,906 shares of Common Stock (based on 863,110 Series C Preferred Shares prior to the Reverse Recapitalization), determined at issuance. The Loan Agreement states the repayment amount is to be the greater of the balance of principal and accrued interest or the Phantom Shares value. We determined that the note should be accounted for at fair value. We record the fair value of the debt at the end of each reporting period. In order to value the note, we consider the amount of the simple interest expense that would be due and the value of Phantom Shares. Upon the closing of the Reverse Recapitalization and as of December 31, 2020, the fair value of the 2019 MD Loan is determined based on the closing price of CLNN shares listed on Nasdaq. Income of $0.2 million and expense of $0.3 million was recognized during the three and six months ended June 30, 2021, respectively. Expense of $0.1 million and $0.1 million was recognized during the three and six months ended June 30, 2020, respectively. The fair value of $1.3 million and $1.1 million of principal and accrued interest is included in long-term notes payable as of June 30, 2021 and December 31, 2020, respectively.

Cecil County Loan

In April 2019, we entered into a loan agreement (the "**2019 Cecil Loan**") with Cecil County, Maryland ("**Cecil**"). Pursuant to the 2019 Cecil Loan, Cecil agreed to provide a $0.1 million term loan. Amounts outstanding under the 2019 Cecil Loan bear simple interest at an annual rate of 8.00%. Under the 2019 Cecil Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include 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 Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on April 30, 2034. The 2019 Cecil Loan establishes "Phantom Shares," based on 23,981 shares of Common Stock (based on 172,622 Series C Preferred Shares prior to the Reverse Recapitalization), determined at issuance. The 2019 Cecil Loan states the repayment amount is to be the greater of the balance of principal and accrued interest or the Phantom Share value. We determined that the note should be accounted for at fair value. We record the fair value of the debt at the end of each reporting period. In order to value the note, we consider the amount of the simple interest expense that would be due and the value of Phantom Shares. Upon the closing of the Reverse Recapitalization and as of December 31, 2020, the fair value of the 2019 Cecil Loan is determined based on the closing price of CLNN shares listed on Nasdaq. Income of $36 thousand and expense of $0.1 million was recognized during the three and six months ended June 30, 2021, respectively. Expense of $11 thousand and $13 thousand was recognized during the three and six months ended June 30, 2020, respectively. The fair value of $0.3 million and $0.2 million of principal and accrued interest is included in long-term notes payable as of June 30, 2020 and December 31, 2020, respectively.

PPP Loan

In May 2020, we entered into a note payable in the amount of $0.6 million (the "**PPP Note**") under the Paycheck Protection Program of the CARES Act (the "**PPP**"). As amended, the PPP permits forgiveness of amounts loaned for payments of payroll and other qualifying expenses within 24 weeks of receipt of loaned funds, given that at least 60% of the total loan is used for payroll. Amounts not forgiven have a repayment period of five years. In January 2021, the full $0.6 million balance of the PPP Note was forgiven and has been recorded as a gain on extinguishment of debt during the six months ended June 30, 2021. There was no gain on extinguishment of debt recorded during the three months ended June 30, 2021.

Avenue Loan

In May 2021, we entered into a loan agreement (the "**2021 Avenue Loan**") with Avenue Venture Opportunities Funds, L.P. 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. We incurred issuance costs for a total of $0.5 million of which $35 thousand have been expensed immediately. The remaining balance from Tranche 1 of $5.0 million and an additional tranche of $10.0 million ("**Tranche 2**") are available at the Company's request until December 31, 2021 and June 30, 2022, respectively. Funding of the remainder of Tranche 1 and entire Tranche 2 is subject to evidence reasonably satisfactory of receipt of an additional $5.0 million financing through Maryland's State Incentive Programs and/or other Maryland State programs and mutual agreement of the Company and Avenue. Funding of Tranche 2 is also subject to (i) our achievement of a statistically significant result on the primary endpoint as defined within the statistical analysis plan for each respective study, or the totality of the results for any study warrant advancement into a subsequent clinical efficacy study, as reasonably determined by the Company and Avenue with respect to at least two of the following studies: (i) RESCUE-ALS or HEALEY-ALS; (ii) REPAIR-PD; or (iii) REPAIR- MS ("**Performance Milestone 1**"); and (ii) our receipt of net proceeds of at least $30 million from the sale and issuance of our equity securities (including any private placement or follow-on offering) between May 2, 2021 and June 30, 2022.

The term loan bears interest of 9.85%. Interest is the higher of the prime rate plus 6.60% or 9.85%. Payments for the loan are interest only for the initial 12 months and can be extended to (i) 12 months (the "**First Interest-only Period Extension**") if we achieve Performance Milestone 1 and (ii) up to 36 months if we achieve the First Interest-only Period Extension and draw Tranche 2. The loan will amortize in equal payments of principal 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, or $0.6 million, is due in addition to the remaining unpaid principal and accrued interest. The final payment provision is related to the loan host and is not bifurcated pursuant to ASC 815.

Pursuant to the agreement, we granted to Avenue a warrant for the purchase of 115,851 shares of Common Stock at an exercise price equal to the lower of (i) $8.63 (which is equal to the five-day VWAP per share, determined as of the end of trading on the last trading day prior to execution of the loan agreement), or (ii) the lowest price per share paid by cash investors for our Common Stock issued in the next bona fide round of equity financing prior to March 31, 2022 (the "**Next Round Price**") (see Note 10 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report). Upon the funding of Tranche 2, the warrant shall be automatically adjusted to include an additional 72,226 shares of Common Stock, which is equal to 5% of the principal amount of Tranche 2, divided by the lower of (i) the five (5)-day VWAP per share; determined as of the end of trading on the last trading day before the date of issuance of Tranche 2; or (ii) the Next Round Price. We accounted for the Tranche 2 warrants at inception of the 2021 Avenue Loan in accordance with ASC 815 (see Note 1 and Note 10 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report). Avenue also has the right, in its discretion, but not the obligation, at any time from time to time from the first- through the third-year anniversary of the agreement, while the loan is outstanding, to convert an amount of up to $5.0 million of the principal amount of the outstanding loan into Common Stock (the "**Conversion Feature**") at a price per share equal to 120% of the stock purchase price set forth in the warrant. The Conversion Feature is subject to (i) the closing price of our Common Stock for each of the seven consecutive trading days immediately preceding the conversion being greater than or equal to the conversion price and (ii) the Common Stock issued in connection with any such conversion not exceeding 20% of the total trading volume of our Common Stock for the twenty-two consecutive trading days immediately prior to and including the effective date of such conversion.

Under the 2021 Avenue Loan, we agreed to affirmative and negative covenants to which we will remain subject upon maturity in the absence of prepayments. These covenants include 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. The financial covenant associated with the loan agreement includes maintaining minimum 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 (including any PIPE or follow-on offering) between May 1, 2021 and June 30, 2022, we shall no longer be subject to financial covenants. We are not in violation of the covenants. The agreement provides for events of default customary for loans of this type, including but not limited to non-payment, breaches, or defaults in the performance of covenants, insolvency, and bankruptcy. 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 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. During the three and the six months ended June 30, 2021, we recorded interest expense of $0.2 million.

Contractual Obligations and Commitments

Except as set forth in Note 8, *Notes Payable*, to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report, there have been no material changes to our contractual obligations and other commitments as of June 30, 2021, as compared to those disclosed in Part II, Item 7 *Management's Discussion and Analysis of Financial Condition and Results of Operations* of our 2020 Annual Report which was filed with the SEC on March 29, 2021.

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.

Off-Balance Sheet Arrangements

During the period presented, we did not have, and we currently do not have, any off-balance sheet arrangements, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Critical Accounting Policies

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 GAAP. The preparation of these 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.

Our most critical accounting policies are described under the heading *Management's Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies* in Part II, Item 7 of our 2020 Annual Report which was filed with the SEC on March 29, 2021. There were no material changes to our critical accounting policies through June 30, 2021 from those discussed in our 2020 Annual Report.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report for a description of recent accounting pronouncements applicable to our business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information required by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2021, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2021, 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 Chief Executive Officer and Chief 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 at and for the periods presented in accordance with U.S. GAAP.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief 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, 2020 and 2019, 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, including (a) lack of a sufficient number of trained professionals with an appropriate level of accounting knowledge, training, and experience to appropriately analyze, record, and disclose accounting matters timely and accurately; and (b) lack of structures, reporting lines, and appropriate authorities and responsibilities to achieve financial reporting objectives. This deficiency in our control environment contributed to the following additional deficiencies (each of which individually represents a material weakness) in our internal control over financial reporting:

- we did not design and maintain formal accounting policies, procedures, and controls to achieve complete, accurate, and timely financial accounting, reporting, and disclosures, including controls over the preparation and review of account reconciliations and journal entries;

- we did not design and maintain effective controls over segregation of duties related to manual journal entries. Specifically, certain personnel have the ability to both prepare and post manual journal entries without an independent review by someone without the ability to prepare and post manual journal entries;

- we did not design and maintain formal accounting policies, processes, and controls to analyze, account for, and disclose complex transactions. Specifically, we did not design and maintain controls to analyze, account for, and disclose warrants to purchase preferred stock and convertible promissory notes with embedded derivatives, including ensuring complete and accurate data was used in the valuations; and

- we did not design and maintain effective controls over certain 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 appropriate personnel of Clene; (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.

The control deficiencies described above resulted in the misstatement of our redeemable convertible preferred stock warrant liability, accrued liabilities, general and administrative expenses, Australian research and development credit, and amounts and classification within our statement of cash flows, and related financial disclosures as of and for the year ended December 31, 2019 and in the misstatement of our prepaid expenses and other current assets, accrued liabilities, earn-out liabilities, redeemable convertible preferred stock warrant liability, general and administrative expenses, amounts and classification within our statement of equity, and amounts and classification within our statement of cash flows, and related financial disclosures as of and for the year ended December 31, 2020. Additionally, 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 is actively engaged and committed to taking the steps necessary to remediate the control deficiencies that constituted the above material weakness. During 2020, we made the following enhancements to our control environment:

- we added finance personnel to the organization to strengthen our internal accounting team, to provide oversight, structure and reporting lines, and to provide additional review over our disclosures to include a Chief Financial Officer and a Manager of SEC Reporting;

- we engaged outside consultants to assist in the design, implementation, and documentation of internal controls that address the relevant risks, are properly designed, and provide for appropriate evidence of performance of the internal control; and

- we engaged outside consultants to assist us in the evaluation of a new Enterprise Resource Planning ("**ERP**") system in order to mitigate the internal control gaps and limitations that cannot be addressed by the current ERP around segregation of duties, and to enhance the information technology general controls environment.

Our remediation activities are continuing during 2021. In addition to the above actions, we expect to engage in 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;

- implementing 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

We are engaged in the process of the design and implementation of our internal control over financial reporting in a manner commensurate with the scale of our operations following the Reverse Recapitalization. During the quarter ended June 30, 2021, we continued the process to implement 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.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We may be subject to legal proceedings, investigations, and claims incidental to the conduct of our business from time to time. There are no material pending legal proceedings to which we are a party or of which any of our property is the subject.

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 2020 Annual Report which was filed with the SEC on March 29, 2021. There have been no material changes to our risk factors since the 2020 Annual Report. 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	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*	Clene Inc. Board of Directors Compensation Program (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed by the registrant on April 22, 2021)
10.2	Loan and Security Agreement, dated as of May 21, 2021, between Clene Inc., Clene Nanomedicine, Inc. and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on May 24, 2021)
10.3**	First Amendment to the Loan and Security Agreement, dated as of June 30, 2021, between Clene Inc., Clene Nanomedicine, Inc. and Avenue Venture Opportunities Fund, L.P.
10.4	Supplement to the Loan and Security Agreement, dated as of May 21, 2021, among Clene Inc., Clene Nanomedicine, Inc., and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant on May 24, 2021)
10.5	Form of Avenue Venture Opportunities Fund, L.P. Warrant to Purchase Shares of Stock of Clene Inc. (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Registrant on May 24, 2021)
10.6	Form of Subscription Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by the Registrant on May 24, 2021)
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).

* Indicates a management contract or a compensatory plan or agreement.

** 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 Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CLENE INC.

Dated: August 9, 2021

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

Dated: August 9, 2021

By: /s/ Ted (Tae Heum) Jeong
Name: Ted (Tae Heum) Jeong
Title: Chief Financial Officer

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 5, 2021

Clene Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-39834	85-2828339
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6550 South Millrock Drive, Suite G50 Salt Lake City, Utah	84121
(Address of principal executive offices)	(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value US$0.0001 per share	CLNN	The Nasdaq Stock Market LLC
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 5, 2021, the Board of Directors (the "Board") of Clene Inc. (the "Company"), upon the recommendation of the Nominating and Corporate Governance Committee of the Board, appointed Vallerie V. McLaughlin, M.D. as a member of the Board, effective August 5, 2021. Dr. McLaughlin will serve as a Class III Director for the remainder of the current three (3) year term until the 2024 Annual Meeting of Stockholders, and until her successor is duly elected and qualified. Dr. McLaughlin was appointed as the third member of the Nominating and Corporate Governance Committee, effective contemporaneously upon her election to the Board.

The Board determined that Dr. McLaughlin qualifies as an independent director under the director independence standards set forth by the U.S. Securities and Exchange Commission and applicable rules of The Nasdaq Stock Market LLC ("Nasdaq"). There are no arrangements or understandings between Dr. McLaughlin and any other person pursuant to which Dr. McLaughlin was appointed as a director. There are no transactions involving Dr. McLaughlin that are reportable under Item 404(a) of Regulation S-K.

In accordance with the Company's Board of Directors Compensation Program (the "Program") for nonemployee directors, and as approved by the Compensation Committee of the Board, Dr. McLaughlin received an award of non-qualified common stock options in connection with her appointment for 45,000 shares of the Company's common stock with an exercise price of $9.37, equal to the closing price of the Company's common stock on Nasdaq on August 5, 2021. The options vest in 36 equal installments on the last day of each calendar month, beginning August 31, 2021, until such shares are fully vested. In connection with the quarterly meeting of the Board on August 5, 2021, Dr. McLaughlin also received awards of non-qualified stock options having a value equal to the Black-Scholes equivalent of (i) $10,000 for service on the Board, and (ii) $1,000 for service on the Nominating and Corporate Governance Committee, with an exercise price of $9.37, equal to the closing price of the Company's common stock on Nasdaq on August 5, 2021. The options vested immediately upon grant.

Item 8.01 Other Events.

On August 5, 2021, the Company issued a press release announcing the appointment of Dr. McLaughlin to the Board. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated August 5, 2021 announcing the appointment of Dr. Vallerie McLaughlin to the Board of Directors
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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 hereunto duly authorized.

Clene Inc.

Date: August 9, 2021

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

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 10, 2021

Clene Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39834**	**85-2828339**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

6550 South Millrock Drive, Suite G50 Salt Lake City, Utah	**84121**
(Address of principal executive offices)	**(Zip Code)**

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value US$0.0001 per share	CLNN	The Nasdaq Stock Market LLC
Warrants, to acquire one-half of one share of Common Stock for $11.50 per share	CLNNW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 1.01 Entry into a Material Definitive Agreement.

Elkton Lease

On August 10, 2021, Clene Nanomedicine, Inc. ("Clene"), a wholly-owned subsidiary of Clene Inc. (the "Company") entered into a lease agreement (the "Elkton Lease") with 100 Chesapeake Blvd LLC ("Chesapeake") for a 74,210 square foot facility located at 100 Chesapeake Boulevard in Elkton, Maryland to increase the Company's manufacturing capability.

Clene will pay monthly common area maintenance ("CAM") expenses for months 1-3 of the lease term, with a reduced base rent for partial occupancy of $34,013 beginning months 4-12. Upon full occupancy or month 13, whichever occurs first, Clene will pay full base rent of $43,298, which will increase by 2.5% each year. Clene's obligation to pay rent under the Elkton Lease will begin on August 10, 2021. Chesapeake will provide Clene with an allowance of $1.0 million for alterations and improvements to the facility, with all improvements subject to approval by Chesapeake. During the term of the Elkton Lease, Clene is responsible for paying certain costs and expenses as specified in the Elkton Lease, including insurance costs, utilities, applicable taxes, certain maintenance and repairs, and a pro-rate share of CAM for the facility.

The Elkton Lease has an initial ten-year term and provides an option to extend or renew for two periods of five years each, subject to provisions of default or non-performance. At the expiration of the seventh year and each year thereafter during the initial ten-year term, subject to certain provisions, Clene will have the option to purchase the facility for approximately $6.7 million. The Elkton Lease includes various other covenants, indemnities, defaults, security deposits, and other provisions customary for lease transactions.

New Principio Lease

On August 10, 2021, Clene entered into a lease agreement (the "New Principio Lease") with Upper Chesapeake Flex One, LLC ("Upper Chesapeake") for a 32,228 square foot facility located at 500 Principio Parkway West in North East, Maryland. Clene currently leases approximately 22,116 square feet at this facility, and the New Principio Lease will result in the termination of Clene's current lease agreement (the "Old Principio Lease"), as amended, effective as of December 1, 2021.

Clene will pay monthly base rent of $35,531 which will increase by 2.5% each year. Clene's obligation to pay rent under the New Principio Lease will begin on December 1, 2021. During the term of the New Principio Lease, Clene is responsible for paying certain costs and expenses as specified in the New Principio Lease, including insurance costs, utilities, applicable taxes, certain maintenance and repairs, and a pro-rate share of CAM for the facility.

The New Principio Lease has an initial seven-year term and provides an option to extend or renew for two periods of five years each, subject to provisions of default or non-performance. The New Principio Lease includes various other covenants, indemnities, defaults, security deposits, and other provisions customary for lease transactions.

The foregoing descriptions of the Elkton Lease and the New Principio Lease do not purport to be complete and are qualified in their entirety by reference to the text of the Elkton Lease and New Principio Lease, which are filed as Exhibit 10.1 and Exhibit 10.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

Item 1.02 Termination of a Material Definitive Agreement.

On August 10, 2021, Clene entered into a lease termination agreement with Upper Chesapeake, pursuant to which the Old Principio Lease will be terminated effective as of November 30, 2021. As the termination was pursuant to the execution of the New Principio Lease with Upper Chesapeake, no early termination penalties were incurred.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information included in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 2.03 of this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On August 11, 2021, the Company issued a press release announcing the Elkton Lease and Principio Lease. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
10.1	Lease Agreement, dated as of August 10, 2021, between Clene Nanomedicine, Inc. and 100 Chesapeake Blvd LLC.
10.2	Lease Agreement, dated as of August 10, 2021, between Clene Nanomedicine, Inc. and Upper Chesapeake Flex One, LLC.
99.1	Press Release dated August 11, 2021.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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 hereunto duly authorized.

Clene Inc.

Date: August 11, 2021

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