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

FORM 10-Q

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

For the quarterly period ended **September 30, 2021**

or

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

For the transition period from _____ to _____

Commission file number: **01-39834**

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

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

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

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

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

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

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

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

The number of shares outstanding of the registrant's Common Stock as of November 4, 2021 was 62,203,532.

CLENE INC.
Quarterly Report on Form 10-Q for the Period Ended September 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)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 60,552	$ 59,275
Accounts receivable	68	21
Inventory	41	191
Prepaid expenses and other current assets	4,732	3,502
Total current assets	65,393	62,989
Restricted cash	58	-
Right-of-use assets	3,340	1,029
Property and equipment, net	4,246	4,225
TOTAL ASSETS	$ 73,037	$ 68,243
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,023	$ 1,124
Accrued liabilities	3,117	3,960
Income tax payable	164	164
Deferred revenue from related parties	112	112
Operating lease obligations, current portion	262	194
Finance lease obligations, current portion	153	190
Clene Nanomedicine contingent earn-out, current portion	-	5,924
Total current liabilities	4,831	11,668
Operating lease obligations, net of current portion	4,068	1,785
Finance lease obligations, net of current portion	125	205
Convertible notes payable	4,559	-
Notes payable	14,613	1,949
Deferred income tax	68	260
Warrant liability	910	-
Clene Nanomedicine contingent earn-out, net of current portion	33,981	46,129
Initial Shareholders contingent earn-out	4,196	5,906
TOTAL LIABILITIES	67,351	67,902
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value: 150,000,000 and 100,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 62,177,020 and 59,526,171 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	6	6
Additional paid-in capital	173,203	153,571
Accumulated deficit	(167,724)	(153,561)
Accumulated other comprehensive income	201	325
TOTAL STOCKHOLDERS' EQUITY	5,686	341
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 73,037	$ 68,243

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	$ 63	$ 81	$ 400	$ 160
Royalty revenue	47	17	124	17
Total revenue	110	98	524	177
Operating expenses:				
Cost of revenue	14	-	812	58
Research and development	6,146	3,994	18,893	10,750
General and administrative	4,400	1,795	16,739	3,623
Total operating expenses	10,560	5,789	36,444	14,431
Loss from operations	(10,450)	(5,691)	(35,920)	(14,254)
Other income (expense), net:				
Interest income (expense)	80	(367)	(497)	(608)
Gain on extinguishment of notes payable	-	-	647	-
Loss on extinguishment of convertible notes payable	-	(540)	-	(540)
Gain on termination of lease	-	-	-	51
Change in fair value of preferred stock warrant liability	-	(5,071)	-	(7,378)
Change in fair value of derivative liability	-	15	-	29
Change in fair value of Clene Nanomedicine contingent earn-out	35,042	-	18,072	-
Change in fair value of Initial Shareholders contingent earn-out	3,439	-	1,710	-
Change in fair value of common stock warrant liability	414	-	547	-
Australia research and development credit	364	1,343	1,078	2,611
Other income (expense), net	(14)	16	(13)	34
Total other income (expense), net	39,325	(4,604)	21,544	(5,801)
Net income (loss) before income taxes	28,875	(10,295)	(14,376)	(20,055)
Income tax benefit	69	-	213	-
Net income (loss)	28,944	(10,295)	(14,163)	(20,055)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(87)	2	(124)	18
Total other comprehensive income (loss)	(87)	2	(124)	18
Comprehensive income (loss)	$ 28,857	$ (10,293)	$ (14,287)	$ (20,037)
Net income (loss) per common share attributable to common shareholders (Note 19)[(1)]:				
Basic	$ 0.47	$ (0.59)	$ (0.23)	$ (1.16)
Diluted	$ 0.42	$ (0.59)	$ (0.23)	$ (1.16)
Weighted average number of common shares outstanding[(1)]:				
Basic	62,071,754	17,358,159	61,307,699	17,358,159
Diluted	70,038,634	17,358,159	61,307,699	17,358,159

(1) Retroactively restated for the three and nine months ended September 30, 2020 for the Reverse Recapitalization as described in Note 3

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income	(Deficit)
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 awards	-	-	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)
Exercise of stock options	-	-	236,976	-	319	-	-	319
Exercise of warrants	-	-	1,002,250	-	10	-	-	10
Exercise of underwriter's option	-	-	54,083	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	2,425	-	-	2,425
Issuance of common stock upon vesting of restricted stock awards	-	-	202,120	-	-	-	-	-
Foreign currency translation adjustment	-	-	-	-	-	-	(87)	(87)
Net income	-	-	-	-	-	28,944	-	28,944
Balances at September 30, 2021	-	$ -	62,177,020	$ 6	$ 173,203	$ (167,724)	$ 201	$ 5,686
Balances at December 31, 2019[1]	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[1]	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[1]	27,499,837	$ 72,661	17,357,505	$ 2	$ 2,099	$ (79,331)	$ 57	$ (77,173)
Issuance of Series D Preferred Stock, net of issuance costs of $1.3 million[1]	7,896,922	35,051	-	-	-	-	-	-
Issuance of Series D Preferred Stock in connection with the extinguishment of convertible promissory notes[1]	1,497,135	6,891	-	-	-	-	-	-
Exercise of stock options[1]	-	-	2,663	-	2	-	-	2
Stock-based compensation expense	-	-	-	-	209	-	-	209
Foreign currency translation adjustment	-	-	-	-	-	-	2	2
Net loss	-	-	-	-	-	(10,295)	-	(10,295)
Balances at September 30, 2020[1]	36,893,894	114,603	17,360,168	2	2,310	(89,626)	59	(87,255)

(1) Retroactively restated for the Reverse Recapitalization as described in Note 3

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (14,163)	$ (20,055)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	734	696
Non-cash lease expense	81	87
Change in fair value of preferred stock warrant liability	-	7,378
Change in fair value of Clene Nanomedicine contingent earn-out	(18,072)	-
Change in fair value of Initial Shareholders contingent earn-out	(1,710)	-
Change in fair value of derivative	-	(29)
Change in fair value of common stock warrant liability	(547)	-
Gain on termination of lease	-	(51)
Stock-based compensation expense	9,945	554
Gain on extinguishment of notes payable	(647)	-
Loss on extinguishment of convertible notes payable	-	540
Accretion of debt discount	-	179
Increase (decrease) in interest accrued on notes payable	(134)	399
Changes in operating assets and liabilities:		
Inventory	150	(32)
Accounts receivable	(48)	(21)
Prepaid expenses and other current assets	(1,230)	(2,112)
Accounts payable	446	(242)
Accrued liabilities	511	(335)
Payable to related parties	-	(131)
Deferred revenue from related parties	-	112
Deferred income tax	(192)	-
Operating lease obligations	(142)	(58)
Net cash used in operating activities	(25,018)	(13,121)
Cash flows from investing activities:		
Purchases of property and equipment	(661)	(269)
Net cash used in investing activities	(661)	(269)
Cash flows from financing activities:		
Proceeds from exercise of stock options	427	2
Proceeds from issuance of convertible notes payable	-	6,125
Proceeds from warrants exercised	10	-
Payments of finance lease obligations	(117)	(156)
Proceeds from the private placement	9,250	-
Proceeds from the issuance of notes payable	20,000	652
Payments of debt issuance costs	(534)	-
Payments of notes payable	(5)	-
Payments of deferred transaction costs	(1,901)	(310)
Proceeds from issuance of Series D Preferred Stock, net of issuance costs	-	35,051
Net cash provided by financing activities	27,130	41,364
Effect of foreign exchange rate changes on cash	(116)	19
Net increase in cash and restricted cash	1,335	27,993
Cash and restricted cash – beginning of period	59,275	8,788
Cash and restricted cash – end of period	$ 60,610	$ 36,781
Reconciliation of cash and restricted cash to the condensed consolidated balance sheets		
Cash	$ 60,552	$ 36,781
Restricted cash	58	-
Cash and restricted cash	$ 60,610	$ 36,781
Supplemental disclosure of non-cash investing and financing activities:		
Warrant liability recorded at issuance of notes payable	$ 1,457	-
Lease liability arising from obtaining right-of-use assets, leasehold improvements, and lease incentives	$ 2,492	$ 820
Lease liability settled through termination of lease	$ -	$ 349
Issuance of derivative instrument related to convertible notes	$ -	$ (705)
Issuance of Series D Preferred Stock upon extinguishment of convertible promissory notes	$ -	$ 5,675
Extinguishment of derivative liability in connection with extinguishment of convertible promissory notes	$ -	$ 676

Deferred offering costs in accrued liabilities	$ -	$ 2,011
Supplemental disclosure:		
Cash paid for interest expense	$ 631	$ 30

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 clinical-stage pharmaceutical company pioneering the discovery, development, and commercialization of novel clean-surfaced nanotechnology therapeutics. We have developed an electro-crystal-chemistry drug development platform which enables production of concentrated, stable, highly active, clean-surfaced nanocrystal suspensions. We have multiple drug assets currently in development for applications in neurology, infectious disease, and oncology. Our efforts are currently focused on addressing the high unmet medical needs in two areas: first, those related to central nervous system disorders including Multiple Sclerosis ("MS"), Parkinson's Disease ("PD") and Amyotrophic Lateral Sclerosis ("ALS"); and second, those related to COVID-19, a highly infectious viral respiratory disease with serious and sometimes fatal co-morbidities. Our patented electro-crystal-chemistry manufacturing platform further enables us to develop very low concentration dietary supplements to advance the health and well-being of broad populations. These dietary supplements can vary greatly and include nanocrystals of varying composition, shapes and sizes as well as ionic solutions with diverse metallic constituents. Dietary supplements are marketed and distributed through our wholly owned subsidiary, dOrbital, Inc. ("dOrbital"), or through an exclusive license with 4Life Research LLC ("4Life"), 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 warrants (the "Public Warrants") and 904,231 warrants (the "Kensington Warrants") were originally issued by Tottenham Acquisition I Limited ("Tottenham") and Clene Nanomedicine, respectively, prior to the closing of the Reverse Recapitalization, and 2,239,500 warrants (the "December 2020 PIPE Warrants") were issued as part of a private placement (the "December 2020 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 nine months ended September 30, 2021, respectively, recognized as an expense within general and administrative expenses in the condensed consolidated statement of operations and comprehensive income (loss) during the three and nine months ended September 30, 2021. As of September 30, 2021, the Company received aggregate proceeds of $10.0 thousand from the exercise of certain warrants, representing 2,004,500 December 2020 PIPE Warrants at an offering price per share of $0.01.

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 warrants (the "AK Warrants", and collectively with the Kensington Warrants, the "Founder Warrants") were originally issued by Clene Nanomedicine prior to the Reverse Recapitalization in April 2013 and 115,851 warrants (the "Avenue Warrants") were issued pursuant to a loan agreement (the "2021 Avenue Loan") with Avenue Venture Opportunities Fund, L.P. ("Avenue") (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 (the "May 2021 PIPE"). We will not receive any proceeds from the possible sale of these shares 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 were recognized as an expense within general and administrative expenses in the condensed consolidated statements of operations and comprehensive income (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 a net loss of $14.2 million for the nine months ended September 30, 2021. We incurred net losses of $10.3 million and $20.1 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, our cash totaled $60.6 million, and our accumulated deficit was $167.7 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 $25.0 million and $13.1 million for the nine months ended September 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 September 30, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date these condensed consolidated financial statements for the three and nine months ended September 30, 2021 were issued.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the 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 condition as of September 30, 2021, the results of our operations for the three and nine months ended September 30, 2021, our cash flows for the nine months ended September 30, 2021 and 2020, and the condensed consolidated statement of stockholders' equity (deficit) for the three and nine months ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2021 and 2020 are unaudited. The results of operations for the three and nine months ended September 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 condition 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 September 30, 2021 and December 31, 2020, we had no cash equivalents.

Restricted Cash

We classify cash as restricted when it is unavailable for withdrawal or use in our general operating activities. Restricted cash and investments are classified as current and noncurrent on the consolidated balance sheets based on the nature of the restriction. Our restricted cash balance includes contractually restricted deposits related to our corporate credit card. As of September 30, 2021 and December 31, 2020, we had restricted cash of $0.1 million and $0, respectively.

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 $26 thousand in raw materials and $14 thousand in finished goods as of September 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.

Deferred Offering Costs

We capitalize certain legal, professional accounting. and other third-party fees that are directly associated with in-process equity financings, including the Reverse Recapitalization and the December 2020 PIPE, as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive income (loss).

During the three and nine months ended September 30, 2021, we did not incur any offering costs. During the three and nine months ended September 30, 2020, we incurred $2.3 million of deferred offering costs related to the Reverse Recapitalization that were comprised of legal and professional accounting fees and other costs.

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: (i) the right to obtain substantially all of the economic benefits from use of the identified asset, and (ii) the right to direct the use of the identified asset. This determination is reassessed if the terms of the contract are changed. Leases are classified as operating or finance leases based on the terms of the lease agreement and certain characteristics of the identified asset. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments less any lease incentives received. At the lease commencement date, the discount rate implicit in the lease is used to discount the lease liability if readily determinable. If not readily determinable or leases do not contain an implicit rate, our incremental borrowing rate is used as the discount rate.

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 within the condensed consolidated balance sheets. We recognize lease expense for these short-term leases on a straight-line basis over the lease term in the condensed consolidated statements of operations and comprehensive income (loss).

Certain lease agreements may require us to pay additional amounts for taxes, insurance, maintenance, and other expenses, which are generally referred to as non-lease components. Such variable non-lease components are treated as variable lease payments and recognized in the period in which the obligation for these payments is incurred. Variable lease components and variable non-lease components are not measured as part of the right-of-use asset and liability. Only when lease components and their associated non-lease components are fixed are they accounted for as a single lease component and are recognized as part of a right-of-use asset and liability. Total contract consideration is allocated to the 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 income (loss), operating lease expense, which is recognized on a straight-line basis over the lease term, and the amortization of finance lease right-of-use assets, which are included in property and equipment and depreciated, are included in research and development or general and administrative expenses consistent with the leased assets' primary use. Accretion on the liabilities for finance leases is included in interest expense.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Property and equipment consist of laboratory 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 laboratory 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 income (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 income (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 income (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 income (loss). 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 income (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 income (loss).

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 nine months ended September 30, 2021 and 2020 was comprised of sales of dietary supplements.

We recorded deferred revenue of $0.1 and $0.1 million as of September 30, 2021 and December 31, 2020 from the dietary supply agreement with the related party (see Note 20).

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 income (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 nine months ended September 30, 2021, we recognized $0.4 million and $1.1 million, respectively, of Australian Research and Development Credit within other income (expense), net in the condensed consolidated statements of operations and comprehensive income (loss). During the three and nine months ended September 30, 2020, we recognized $1.3 million and $2.6 million, respectively, of Australian Research and Development Credit within other income (expense), net in the condensed consolidated statements of operations and comprehensive income (loss). As of September 30, 2021, and December 31, 2020, we recorded $1.2 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 September 30, 2021 and December 31, 2020, we recorded $0.6 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 income (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 nine months ended September 30, 2021, we recorded a grant of $0 and $0.2 million, respectively, as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive income (loss). During the three and nine months ended September 30, 2020, we recorded a grant of $0.2 million and $0.7 million, respectively, as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive income (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 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 income (loss) as incurred.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (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 Income (Loss) Per Share Attributable to Common Shareholders

Basic net income (loss) per share attributable to common shareholders is calculated using our weighted-average outstanding common shares. Diluted net income (loss) per share attributable to common shareholders is calculated using our weighted-average outstanding common shares including the dilutive effect of securities as determined under the treasury stock method, except for the dilutive effect of convertible notes payable, which is calculated under the if-converted method, even if the embedded conversion option is out-of-the-money. 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.

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 stock awards. Stock-based compensation expense is recorded in research and development and general and administrative expenses based on the classification of the work performed by the grantees.

The fair value is recognized over the period during which a grantee was required to provide services in exchange for the option award and service-based stock awards, known as the requisite service period (usually the vesting period), on a straight-line basis. For stock awards with market conditions, the fair value is recognized over the period based on the expected milestone achievement dates as the derived service period (usually the vesting period), on a straight-line basis. For stock awards with performance conditions, the grant-date fair value of these awards is the market price on the applicable grant date, and compensation expense will be recognized when the conditions become probable of being satisfied. We will recognize a cumulative true-up adjustment once the conditions become probable of being satisfied as the related service period had been completed in a prior period.

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 Market LLC ("Nasdaq") on the date of grant. The fair value of stock awards 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 laboratory 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 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. For smaller reporting companies, 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. We 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 December 2019, the FASB issued ASU 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. The new guidance was effective for our fiscal year, and interim periods within our fiscal year, beginning after December 15, 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 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 our fiscal year beginning after December 15, 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 2018-13, *Fair Value Measurement (Topic 820)*. The new guidance improves the effectiveness of disclosures about fair value measurements required under ASC 820. The new guidance amends the disclosure requirements for recurring and nonrecurring fair value measurements by removing, modifying, and adding certain disclosures. The new guidance was effective for our fiscal year, and interim periods with our fiscal year, beginning after December 15, 2019. 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 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.

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. Prior to the Reverse Recapitalization, there was not a public market for the shares of Clene Nanomedicine common stock.

The Reverse Recapitalization was effected in two steps: (i) Tottenham was reincorporated to the state of Delaware by merging with and into PubCo (the "Reincorporation Merger"); and (ii) promptly following the Reincorporation Merger, Merger Sub was merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine becoming a wholly-owned subsidiary of PubCo (the "Acquisition Merger"). On the Closing Date, PubCo changed its name from Chelsea Worldwide Inc. to Clene Inc. and listed its shares of Common Stock, par value $0.0001 per share on Nasdaq under the symbol "CLNN."

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 agreed to issue rights to 370,101 restricted stock awards 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 rights to 1,136,961 restricted stock awards to option holders to complement the earn-out payments that would contingently be issued to certain current Clene Nanomedicine 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 December 2020 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.

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 in historical periods prior to the Reverse Recapitalization have been retroactively restated using 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.

Between July 1, 2021 and September 15, 2021, various investors exercised December 2020 PIPE Warrants for 1,002,250 shares of Common Stock at an exercise price of $0.01 per share. The December 2020 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 $10.0 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.

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 September 30, 2021 and December 31, 2020:

(in thousands)	September 30, 2021	December 31, 2020
Australia research and development credit receivable	$ 1,212	$ 2,148
CRO prepayments	693	1,211
Metals to be used in research and development	1,691	31
Directors & Officers Insurance	934	-
Other	202	112
	$ 4,732	$ 3,502

5. Property and Equipment, Net

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

(in thousands)	September 30, 2021	December 31, 2020
Laboratory equipment	$ 3,183	$ 3,077
Furniture and fixtures	147	147
Leasehold improvements	3,927	3,889
Construction in progress	1,061	490
	8,318	7,603
Less accumulated depreciation	(4,072)	(3,378)
Total property and equipment, net	$ 4,246	$ 4,225

Depreciation expense related to property and equipment, net for the three and nine months ended September 30, 2021 was approximately $0.2 million and $0.7 million, respectively. Depreciation expense is reported in research and development expense and in general and administrative expense for $0.6 million and $0.1 million, respectively, for the nine months ended September 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 September 30, 2021, in the condensed consolidated statements of operations and comprehensive income (loss).

Depreciation expense related to property and equipment, net for the three and nine months ended September 30, 2020 was approximately $0.2 million and $0.7 million, respectively. Depreciation expense is reported in research and development expense and in general and administrative expense for $0.6 million and $47 thousand, respectively, for the nine months ended September 30, 2020; and in research and development expense and in general and administrative expense for $0.2 million and $34 thousand, respectively, for the three months ended September 30, 2020, in the condensed consolidated statements of operations and comprehensive income (loss).

6. Accrued Liabilities

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

(in thousands)	September 30, 2021	December 31, 2020
Accrued professional fees	$ -	$ 189
Accrued compensation and benefits	1,744	1,225
Accrued CRO fees	675	788
Deferred grant funds	601	301
Accrued expense reimbursements	33	33
Accrued transaction costs	-	1,354
Other	64	70
	$ 3,117	$ 3,960

7. Leases

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

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.

In August 2021, we entered into an operating lease for laboratory space. At the time of commencement, we recorded a right-of-use asset value of $2.4 million and a lease liability of $2.4 million, net of a lease incentive of $1.0 million. The lease incentive represents an allowance from the lessor for facility alterations. As the lease incentive is payable based on events within our control and are deemed reasonably certain to occur, we recorded the lease incentive as a reduction of the right-of-use asset and lease liability at the lease commencement. As of September 30, 2021, we incurred $0.1 million of costs related to the lease incentive which we recorded as construction in progress, with a corresponding increase to the lease liability, and the construction in progress will be capitalized as leasehold improvements when the facility is placed into service. The lease has an initial ten-year term and provides us the right and option to extend or renew for two periods of five years each. In accordance with ASC 842, the payments to be made in option periods have not been recognized as part of the right-of-use asset or lease liability because we do not assess the exercise of the option to be reasonably certain.

Additionally, in August 2021, we entered into an operating lease for laboratory space that will replace a previous operating lease for the same facility. The commencement of the new lease and the termination of the previous lease will be effective as of December 1, 2021, and had no impact on the condensed consolidated financial statements for the three and nine months ended September 30, 2021.

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

(in thousands)	**Finance Leases**	**Operating Leases**
2022	$ 43	870
2023	136	960
2024	82	982
2025	20	1,007
2026	-	1,031
Thereafter	-	2,887
Total undiscounted cash flows	281	7,737
Less amount representing interest/discounting	(3)	(2,507)
Present value of future lease payments	278	5,230
Less future lease incentives	-	(900)
Less lease obligations, current portion	(153)	(262)
Lease obligations – long term portion	$ 125	$ 4,068

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 September 30, 2021 and December 31, 2020 are summarized as follows:

(in thousands)	September 30, 2021	December 31, 2020
Laboratory equipment	$ 1,148	$ 920
Furniture and fixtures	46	46
Work in process	-	228
Total	1,194	1,194
Less accumulated depreciation	(629)	(593)
Net	$ 565	$ 601

As of September 30, 2021, our finance lease obligations had a weighted-average interest rate of 8.6% and had a weighted-average remaining term of 2.2 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 September 30, 2021, our operating lease obligations had a weighted-average discount rate of 9.6% and had a weighted-average remaining term of 8.3 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 nine months ended September 30, 2021 and 2020 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2021	2020	2021	2020
Finance lease costs:				
Amortization	$ 37	$ 41	$ 110	$ 137
Interest on lease liabilities	6	9	21	30
Operating lease costs	107	95	247	308
Short-term lease costs	98	66	214	203
Variable lease costs	32	22	71	70
Total lease costs	$ 280	$ 233	$ 663	$ 748

Supplemental Cash Flow Information

(in thousands)	2021	2020
Operating cash flows from operating leases	$ (533)	$ (497)
Operating cash flows from finance leases	$ (21)	$ (30)
Financing cash flows from finance leases	$ (117)	$ (156)

8. Notes Payable

Our long-term debt, net of original issue discount and unamortized debt issuance costs, consisted of the following:

(in thousands)	Interest Rate	September 30, 2021	December 31, 2020
Term Loans:			
Maryland Department of Housing & Community Development	8.00%	$ 819	$ 1,080
Advance Cecil, Inc.	8.00%	164	216
Paycheck Protection Program	1.00%	-	647
Avenue Venture Opportunities Fund, L.P.	9.85%	20,000	-
Other	0.00%	-	6
		20,983	1,949
Unamortized debt issuance costs and original issue discounts		(1,811)	-
Less convertible notes payable, net of unamortized debt discount and issuance costs (see Note 11)		(4,559)	-
Total notes payable		$ 14,613	1,949

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 2019 MD Loan. Events of default under the 2019 MD Loan include failure to make payments when due, insolvency events, and failure to comply with covenants. We are not in violation of any affirmative 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 2019 MD Loan 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 $0.5 million and $0.3 million were recognized during the three and nine months ended September 30, 2021, respectively. Expense of $0.2 million and $0.3 million was recognized during the three and nine months ended September 30, 2020, respectively. The fair value of $0.8 million and $1.1 million of principal and accrued interest is included in long-term notes payable as of September 30, 2021 and December 31, 2020, respectively.

Cecil County Loan

In April 2019, we entered into a loan agreement (the "2019 Cecil Loan") with Advance Cecil Inc., a non-stock corporation formed under the laws of the state of Maryland with application for 501(c)(3) non-profit status pending before the United States Internal Revenue Service at the time of execution of the 2019 Cecil Loan. 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 covenants to which we will remain subject until maturity. These covenants include providing information about the Company and our operations. There are no financial covenants associated with the 2019 Cecil Loan. Events of default under the 2019 Cecil Loan 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 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 $0.1 million and expense of $52 thousand were recognized during the three and nine months ended September 30, 2021, respectively. Expense of $42 thousand and $55 thousand was recognized during the three and nine months ended September 30, 2020, respectively. The fair value of $0.2 million and $0.2 million of principal and accrued interest is included in long-term notes payable as of September 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 nine months ended September 30, 2021. There was no gain on extinguishment of debt recorded during the three months ended September 30, 2021.

Avenue Loan

In May 2021, we entered into the 2021 Avenue Loan with Avenue. The agreement provides for a 42-month term loan of up to $30.0 million. The first tranche is $20.0 million ("Tranche 1"), of which $15.0 million was funded at close. We incurred issuance costs for a total of $0.5 million of which $35 thousand has been expensed immediately. The remaining balance from Tranche 1 of $5.0 million was funded on September 28, 2021 and an additional tranche of $10.0 million ("Tranche 2") is available at the Company's request until June 30, 2022. Pursuant to the 2021 Avenue Loan, funding of Tranche 2 is subject to evidence reasonably satisfactory to Avenue 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. On September 27, 2021, we obtained a waiver from this additional financing requirement for the funding of the remaining $5.0 million of Tranche 1 and exercised the option to postpone principal repayment by one year. We incurred additional issuance costs of $75 thousand upon funding the remaining $5.0 million of Tranche 1, of which $12 thousand has been expensed immediately. Funding of Tranche 2 is also subject to (a) 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 the Healey ALS Platform Trial; (ii) REPAIR-PD; or (iii) REPAIR-MS ("Performance Milestone 1"); and (b) 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 loans bear interest at a variable rate per annum equal to the sum of (i) the greater of (A) the prime rate, as published by the Wall Street Journal from time to time or (B) 3.25%, plus (ii) 6.60%. 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 (a) we achieve the First Interest-only Period Extension and (b) have drawn from Tranche 2. On August 16, 2021, we mutually confirmed with Avenue that Performance Milestone 1 and the First Interest-only Period Extension had been achieved. 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 the Avenue Warrants 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 volume weighted average price ("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 Avenue Warrant shall be automatically adjusted to include an additional estimated 86,679 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 and the fair value and issuable shares will be remeasured at each reporting period (see 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, the occurrence of a material adverse change, or defaults in the performance of covenants, insolvency, and bankruptcy. The 2021 Avenue Loan is collateralized by substantially all of our assets other than intellectual property, including capital stock of the Company and its subsidiaries, in which Avenue is granted a continuing security interest. The net proceeds from the issuance of the loan were initially allocated to the warrant at an amount equal to their fair value of $1.0 million and the remainder to the loan. The allocation of incurred financing costs of $0.5 million and the fair value of the warrant, together with 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 nine months ended September 30, 2021, we recorded interest expense of $0.6 million and $0.8 million, respectively.

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)	**September 30, 2021**
2021 (remainder)	$ -
2022	-
2023	6,667
2024	13,333
2025	-
2026	-
Thereafter	-
Subtotal of future principal payments	$ 20,000
Unamortized debt discount associated with issuance date warrant fair value and financing costs	(1,811)
Total	$ 18,189

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 income (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 income (loss). Upon the closing of the Reverse Recapitalization, the warrant liability was reclassified to additional paid-in capital (see Note 17).

As of September 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 $5.1 million during the three months ended September 30, 2020 and $7.4 million during the nine months ended September 30, 2020 in the condensed consolidated statements of operations and comprehensive income (loss).

10. Common Stock Warrants

As of September 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	117,500(1)	$ 0.01	Common Stock	Equity	December 2021
December 2020	2,407,500(2)	$ 11.50	Common Stock	Equity	December 2025
December 2020	24,583(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	4,594,545				

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) Consisted of 1,119,750 shares of Common Stock underlying 2,239,500 December 2020 PIPE Warrants issued on December 30, 2020, in connection with the December 2020 PIPE (see Note 18). A holder of the December 2020 PIPE Warrants may not exercise the 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 September 30, 2021, 2,004,500 December 2020 PIPE Warrants were exercised into 1,002,250 shares of Common Stock. The outstanding balance as of September 30, 2021 consists of 117,500 shares of Common Stock underlying 235,000 December 2020 PIPE Warrants. As of 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 September 30, 2021, and December 31, 2020, none of the warrants had been exercised.

(3) Consisted of 110,000 shares of Common Stock underlying 220,000 warrants issued as part of the Chardan Unit Purchase Option (see Note 3). On July 15, 2021 the Chardan Unit Purchase Option was net exercised, resulting in the issuance of 54,083 shares of Common Stock and 49,166 warrants to purchase one-half of one share of Common Stock, or 24,583 shares of Common Stock. As of September 30, 2021, none of the warrants had been exercised. As of 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 September 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 Avenue 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 September 30, 2021, the Avenue Warrant had not been exercised.

(6) Pursuant to the 2021 Avenue Loan, an additional estimated 86,679 shares of Common Stock underlying 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 and the fair value and issuable shares will be remeasured at each reporting period (see Note 16). As of September 30, 2021, the warrants are 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 September 30, 2020, in connection with the 2020 Convertible Notes. We recognized interest expense of $0.1 million, including amortization of debt discount of $0.2 million during the nine months ended September 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 income (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 Avenue 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 September 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 September 30, 2021, with unamortized debt discount and issuance costs of $0.4 million.

During the three and nine months ended September 30, 2021, we recognized (i) total interest expense of $0.2 million and $0.3 million, respectively; (ii) coupon interest expense of $0.1 million and $0.2 million, respectively; and (iii) amortization of debt discount and issuance costs of $41 thousand and $64 thousand, respectively, in connection with the convertible notes payable. During the three and nine months ended September 30, 2020, we did not recognize any interest expense or amortization in connection with the convertible notes payable. The effective interest rate was 15.46% for the three and nine months ended September 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 income (loss) for the year ended December 31, 2020 (see Note 11). For the three and nine months ended September 30, 2020, we recorded the change in the 2020 Derivative Instrument of $15 thousand and $29 thousand, respectively, in the condensed consolidated statements of operations and comprehensive income (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 income (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 September 30, 2021, the carrying values of the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out were $34.0 million and $4.2 million, respectively. For the three months ended September 30, 2021, we recognized gains of $35.0 million in change in fair value of the Clene Nanomedicine Contingent Earn-out and $3.4 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 income (loss). For the nine months ended September 30, 2021, we recognized gains of $18.1 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 income (loss). To date, none of the milestones have been achieved.

Derivative Instrument in Connection with the 2021 Avenue Loan

The Avenue Warrants issued pursuant to Tranche 1 of the 2021 Avenue Loan and the warrants issuable pursuant to the draw of Tranche 2 (see Note 8) met the requirements for separate accounting and are therefore accounted for as derivative instruments. 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 nine months ended September 30, 2021, we recognized income of $0.4 million and $0.5 million, respectively, 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 income (loss). To date, the warrants have 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 $0.2 million for the net operating losses incurred for the three and nine months ended September 30, 2021. We have not recorded income tax benefits for the net operating losses incurred during the three and nine months ended September 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 nine months ended September 30, 2021 and 2020 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
United States	$ 29,860	(11,370)	(11,435)	(20,724)
Foreign	(985)	1,075	(2,941)	669
Total loss before income taxes	$ 28,875	$ (10,295)	$ (14,376)	$ (20,055)

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, restricted stock units, 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 September 30, 2021, the Company's Board of Directors granted rights to 3,819,930 restricted stock awards and stock options under the 2020 Stock Plan. As of September 30, 2021, 8,180,070 shares remained available for future grant.

As of December 31, 2020, the Company's Board of Directors granted rights to 1,507,062 restricted stock awards 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 September 30, 2021 and 2020 was approximately $2.4 million and $0.2 million, respectively, and approximately $9.9 million and $0.6 million for the nine months ended September 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 income (loss) as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Research and development	$ 858	$ 134	$ 3,861	$ 364
General and administrative	1,567	75	6,084	190
Total stock-based compensation	$ 2,425	$ 209	$ 9,945	$ 554

Stock Options

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

Equity	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Term (Years)	Intrinsic Value
Outstanding - December 31, 2020	7,032,591	$ 0.97	5.34	$ 62,462
Granted	2,574,441	8.85	9.61	-
Exercised	(409,867)	1.04	-	2,373
Forfeited	(133,742)	8.66	-	-
Outstanding - September 30, 2021	9,063,423	$ 3.09	5.90	$ 38,863
Options vested and exercisable - September 30, 2021	6,000,723	$ 0.82	4.33	$ 36,247
Stock options vested and expected to vest - September 30, 2021	9,063,423	$ 3.09	5.90	$ 38,863

As of September 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 2.33 years 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 nine months ended September 30, 2021, we granted stock options for 2,574,441 shares under the 2020 Stock Plan. The assumptions used to calculate the value of the stock option awards granted for the nine months ended September 30, 2021 are presented as follows:

	Nine months ended September 30, 2021
Expected stock price volatility	84.8 – 87.4%
Risk-free interest rate	0.59 – 0.94%
Expected dividend yield	0.00%
Expected term	6.00 years

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

Restricted Stock Awards

On December 30, 2020, we granted rights to awards of the following shares of restricted stock 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 restricted stock awards 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 September 30, 2021, there were 224,109 shares of Common Stock issued upon the vesting of restricted stock awards. 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 September 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 September 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 share 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 September 30, 2021 and December 31, 2020 measurement dates, no shares were vested.

The following table summarizes the restricted stock award activity during the nine months ended September 30, 2021:

	Number of Restricted Stock Awards	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	(224,109)	-
Forfeited	(37,464)	10.82
Outstanding and unvested balance as of September 30, 2021	1,245,489	$ 10.14

The assumptions used to calculate the value of the rights to restricted stock awards 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 rights to restricted stock awards granted as of December 31, 2020 was $10.3034.

The stock-based compensation expense associated with the rights to restricted stock awards was $0.8 million and $6.8 million for the three and nine months ended September 30, 2021. As of September 30, 2021 and December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was $0.9 million and $15.5 million, respectively, 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 restricted stock awards during the nine months ended September 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 2019 MD Loan, the 2019 Cecil Loan, the derivative instruments associated with the 2021 Avenue Loan, and the derivative instruments associated with the Contingent Earn-outs are carried at fair value. The 2021 Avenue Loan, related convertible notes payable, and Conversion Feature are carried at amortized cost, which approximate fair value due to our credit risk and market interest 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 September 30, 2021 and December 31, 2020:

	Fair Value Measurements on a Recurring Basis September 30, 2021			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Notes payable	$ 983	$ -	$ -	$ 983
Warrant liability	-	-	910	910
Clene Nanomedicine contingent earn-out	-	-	33,981	33,981
Initial Shareholders contingent earn-out	-	-	4,196	4,196

	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 September 30, 2021 and December 31, 2020.

Valuation of Notes Payable and Convertible Notes Payable

The carrying value of notes payable and convertible notes payable includes certain notes carried at amortized cost, and certain notes remeasured at fair value on a recurring basis in the condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020. In order to value the notes, we considered the amount of simple interest expense that would be due and the value of our Common Stock.

As of September 30, 2021 and December 31, 2020, the fair value of the 2019 MD Loan and the 2019 Cecil Loan was determined based on the closing prices of $6.83 and $9.01 per share, respectively, as reported by Nasdaq.

As of September 30, 2021, the amortized cost of the 2021 Avenue Loan was $18.2 million, which includes the notes payable, carried at $13.6 million; and the convertible notes payable and embedded Conversion Feature, carried at $4.6 million. The valuation of the Conversion Feature is discussed below. The 2021 Avenue Loan was not outstanding as of December 31, 2020.

Valuation of Conversion Feature

The Conversion Feature of the convertible notes payable from the 2021 Avenue Loan is carried at amortized cost and did not meet the requirements for separate accounting and is not accounted for as a derivative instrument. The estimated fair value of the Conversion Feature was $2.0 million and 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 unobservable inputs to the model were as follows:

Black-Scholes Valuation Model

	September 30, 2021	December 31, 2020
Expected stock price volatility	85.00%	N/A
Risk-free interest rate	0.50%	N/A
Expected dividend yield	0.00%	N/A
Expected term	2.56 years	N/A

Monte Carlo Simulation

	September 30, 2021	December 31, 2020
Expected stock price volatility	35.00%	N/A
Risk-free interest rate	0.07%	N/A
Expected dividend yield	0.00%	N/A
Expected term	0.09 years	N/A

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 determined 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 was 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 income (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 the Avenue Warrants 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 an estimated 86,679 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 the fair value and issuable shares 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 September 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

	September 30, 2021	December 31, 2020
Expected stock price volatility	95.00%	N/A
Risk-free interest rate	0.90%	N/A
Expected dividend yield	0.00%	N/A
Expected term	3.89 years – 4.56 years	N/A

Monte Carlo Simulation

	September 30, 2021	December 31, 2020
Expected stock price volatility	40.00 – 70.00%	N/A
Risk-free interest rate	0.07%	N/A
Expected dividend yield	0.00%	N/A
Expected term	0.09 years – 0.66 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 September 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 September 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:

	September 30, 2021	December 31, 2020
Expected stock price volatility	95.00%	85.00%
Risk-free interest rate	0.80%	0.40%
Expected dividend yield	0.00%	0.00%
Expected term	4.2 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 nine months ended September 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	(313)	(18,072)	(1,710)	(547)
Balance - September 30, 2021	$ 983	$ 33,981	$ 4,196	$ 910

(in thousands)	Notes Payable	Derivative Instrument	Preferred Stock Warrants
Balance - December 31, 2019	$ 640	$ -	$ 3,213
Issuance of convertible promissory notes	-	705	-
Change in fair value	323	(29)	7,378
Extinguishment of derivative liability in connection with extinguishment of convertible promissory notes	-	(676)	-
Balance - September 30, 2020	$ 963	$ -	$ 10,591

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 September 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 September 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 "December 2020 PIPE Shares") at a price of $10.00 per share with net proceeds of $22.2 million. The purpose of the December 2020 PIPE was to fund general corporate expenses. In addition, investors in the December 2020 PIPE offering also received warrants to purchase a number of shares equal to one-half (1/2) of the number of December 2020 PIPE Shares, totaling 1,119,750 shares of Common Stock, at an exercise price of $0.01 per share, subject to a 180-day holding period (see Note 10).

On May 21, 2021, the Company entered into the May 2021 PIPE 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 May 2021 PIPE occurred substantially concurrently with, and was conditioned upon, the closing of the 2021 Avenue Loan (see Note 8). The purpose of the May 2021 PIPE was to fund the expansion of manufacturing capabilities in the state of Maryland and to fund general corporate expenses.

Between July 1, 2021 and September 15, 2021, various investors exercised December 2020 PIPE Warrants for 1,002,250 shares of Common Stock at an exercise price of $0.01 per share. The December 2020 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 $10.0 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.

As of September 30, 2021 and December 31, 2020, our common shares issued and outstanding were 62,177,020 and 59,526,171, respectively. As of September 30, 2021 and December 31, 2020, there were no preferred shares issued and outstanding (see Note 17).

19. Net Income (Loss) Per Share Attributable to Common Shareholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator :				
Net income (loss) attributable to common shareholders – Basic	$ 28,944	$ (10,295)	$ (14,163)	$ (20,055)
Less interest expense on potentially dilutive convertible notes payable	$ 196	$ -	$ -	$ -
Net income (loss) attributable to common shareholders - Diluted	$ 29,140	$ (10,295)	$ (14,163)	$ (20,055)
Denominator:				
Weighted average common shares outstanding –Basic	62,071,754	17,358,159	61,307,699	17,358,159
Weighted average effect of potentially dilutive securities:				
Effect of potentially dilutive stock options	5,791,023	-	-	-
Effect of potentially dilutive common stock warrants	1,485,049	-	-	-
Effect of potentially dilutive convertible notes payable	482,703	-	-	-
Effect of potentially dilutive restricted stock awards	208,105	-	-	-
Weighted average common shares outstanding –Diluted	70,038,634	17,358,159	61,307,699	17,358,159
Net income (loss) per share attributable to common shareholders:				
Basic	$ 0.47	$ (0.59)	$ (0.23)	$ (1.16)
Diluted	$ 0.42	$ (0.59)	$ (0.23)	$ (1.16)

Included within weighted average common shares outstanding are the remaining 117,500 (originally 1,119,750) common shares issuable upon the exercise of the December 2020 PIPE Warrants, as these 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.

The following shares of potentially dilutive securities were excluded from the computation of diluted net income (loss) per share attributable to common shareholders for the periods presented because including them would have been antidilutive, or issuance of such shares is contingent upon the satisfaction of certain conditions which were not satisfied by the end of the period, or they were out-of-the money:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Series D redeemable convertible preferred stock	-	9,394,057	-	9,394,057
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 D redeemable convertible preferred stock warrants	-	320,441	-	320,441
Series A redeemable convertible preferred stock warrants	-	1,608,670	-	1,608,670
Convertible notes payable (see Note 11)	-	-	482,703	-
Common stock warrants (see Note 10)	2,523,351	-	4,569,962	-
Options to purchase common stock	2,685,575	7,509,810	9,063,423	7,509,810
Restricted stock awards	1,100,050	-	1,245,489	-
Chardan Unit Purchase Option Warrants (see Notes 3 and 10)	24,583	-	24,583	-
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	15,429,744	46,332,815	24,482,345	46,332,815

20. Related Party Transactions

For the three and nine months ended September 30, 2020, we incurred $0 and $0.1 million, respectively, of expenses for compensation for consulting services provided by a member of the Board of Directors. These expenses were paid in their entirety and as of September 30, 2020 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 nine months ended September 30, 2021, we sold $0.1 million and $0.4 million of product, respectively, under this agreement. We did not sell any products outside of this agreement. For the three and nine months ended September 30, 2021, the investor has made commercial sales of their products under the agreement which we recognized as royalty revenues of $47 thousand and $0.1 million, respectively.

For the nine months ended September 30, 2020, we sold $0.1 million of product under this agreement, as well as $0.1 million 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 September 30, 2020. The investor did not make sales of their products under the agreement, and as such we did not recognize any royalty revenues for the nine months ended September 30, 2020. For the three months ended September 30, 2020, we did not sell any product under this agreement, we sold $2 thousand of product not 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 were as follows:

(in thousands)	**As of September 30, 2021**	**As of December 31, 2020**
United States	$ 4,193	$ 3,997
Australia	53	228
Total property and equipment, net	$ 4,246	$ 4,225

Segment Information

The operating results of the Drugs and Supplements segments were as follows:

(in thousands)	For the Three Months ended September 30, 2021			For the Nine Months ended September 30, 2021		
	Drugs	Supplements	Total	Drugs	Supplements	Total
Revenue from external customers	$ -	$ 110	$ 110	$ -	$ 524	$ 524
Income (loss) from operations	$ (10,546)	$ 96	$ (10,450)	$ (35,632)	$ (288)	$ (35,920)

(in thousands)	For the Three Months ended September 30, 2020			For the Nine Months ended September 30, 2020		
	Drugs	Supplements	Total	Drugs	Supplements	Total
Revenue from external customers	$ -	$ 98	$ 98	$ -	$ 177	$ 177
Income (loss) from operations	$ (5,789)	$ 98	$ (5,691)	$ (14,373)	$ 119	$ (14,254)

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

(in thousands)	As of September 30, 2021	As of December 31, 2020
Drugs	$ 4, 038	$ 3,990
Supplements	208	235
Total property and equipment, net	$ 4,246	$ 4,225

22. Subsequent Events

On October 1, 2021, various investors exercised December 2020 PIPE Warrants for 25,000 shares of Common Stock at an exercise price of $0.01 per share. The December 2020 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 $250.

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 contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), 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.

Business Overview

We are a clinical-stage pharmaceutical company pioneering the discovery, development, and commercialization of novel, clean-surfaced nanocrystal ("CSN®") therapeutics. CSN® therapeutics are comprised of atoms of transition elements that, when assembled in nanocrystal form, possess unusually high, unique catalytic activities not present in those same elements in bulk form. These catalytic activities drive, support, and maintain beneficial metabolic and energetic cellular reactions within diseased, stressed, and damaged cells.

Our patent-protected, proprietary position affords us the potential to develop a broad and deep pipeline of novel CSN® therapeutics to address a range of diseases with high impact on human health. We began in 2013 by innovating an electro-crystal-chemistry drug development platform that draws from advances in nanotechnology, plasma and quantum physics, material science, and biochemistry. Our platform process results in nanocrystals with faceted structures and surfaces that are free of the chemical surface modifications that accompany other production methods. Many traditional methods of nanoparticle synthesis involve the unavoidable deposition of potentially toxic organic residues and stabilizing surfactants on the particle surfaces. Synthesizing stable nanocrystals that are both nontoxic and highly catalytic has overcome this significant hurdle in harnessing transition metal catalytic activity for human therapeutic use.

Our clean-surfaced nanocrystals exhibit catalytic activities many-fold higher than multiple other commercially available nanoparticles, produced using various techniques, that we have comparatively evaluated. We now have multiple drug assets currently in development and/or clinical trials for applications in neurology, infectious disease, and oncology. Our development and clinical efforts are currently focused on addressing the high unmet medical needs in two areas: first, those related to central nervous system disorders including Multiple Sclerosis ("MS"), Parkinson's Disease ("PD"), and Amyotrophic Lateral Sclerosis ("ALS"); and second, those related to COVID-19, a highly infectious viral respiratory disease with serious and sometimes fatal co-morbidities.

We currently have no drugs approved by the FDA 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 $10.5 million and $35.9 million for the three and nine months ended September 30, 2021. Our total loss from operations was $5.7 million and $14.3 million for the three and nine months ended September 30, 2020. Substantially all of our losses from operations resulted from research and development expenses and administrative expenses. As of September 30, 2021 and December 31, 2020, we had an accumulated deficit of $167.7 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 Pandemic

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the COVID-19 outbreak. The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the COVID-19 pandemic and its effects on our business and operations remain uncertain. The COVID-19 pandemic may affect our ability to initiate and complete preclinical studies, delay the initiation of future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In particular, we and our third-party 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 COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds to support our operations. Moreover, the COVID-19 pandemic has significantly impacted economies worldwide and could result in adverse effects on our business and operations.

We are monitoring the potential impact of the COVID-19 pandemic on our business 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 COVID-19 pandemic. We are not aware of any specific related event or circumstance that would require us to revise the estimates reflected in our 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 were to be issued and held in escrow to satisfy any indemnification obligations incurred under the Merger Agreement. The escrowed shares were released without restrictions following the six month anniversary of the completion of the Reverse Recapitalization.

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 agreed to issue rights to 370,101 restricted stock awards under the 2020 Plan 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 rights to 1,136,961 restricted stock awards to option holders to complement the earn-out payments that would contingently be issued to certain current Clene Nanomedicine shareholders upon the achievement of milestones. See "Earn-out Shares" for the milestones detail.

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

On May 21, 2021, the Company entered into the May 2021 PIPE 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 approximately $9.3 million. The closing of the May 2021 PIPE 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 as of September 30, 2021 included in Part I, Item 1 of this Quarterly Report). The purpose of the May 2021 PIPE was to fund the expansion of manufacturing capabilities in the state of Maryland and to fund general corporate expenses.

Between July 1, 2021 and September 15, 2021, various investors exercised December 2020 PIPE Warrants for 1,002,250 shares of Common Stock at an exercise price of $0.01 per share. The December 2020 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 $10.0 thousand.

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 income (loss) for the three and nine months ended September 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 which results in a statistically significant finding of clinical efficacy within twelve months after the closing of the Reverse Recapitalization.

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, if the milestones described above are achieved.

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 approximately $9.3 million from the May 2021 PIPE offering; and
- gross cash proceeds of $20.0 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 trials 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. We communicated that decision to the Department of Defense and the awarded grant was terminated effective July 19, 2021. 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 condition or to the results of our operations or our cash flows for any period.

The net cash used in our operating activities was $25.0 million and $13.1 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had cash of $60.6 million. We expect that the cash on hand as of September 30, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date the condensed consolidated financial statements for the three and nine months ended September 30, 2021 were 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 restricted stock award 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 and $0.2 million of grant funding against research and development expenses for the three and nine months ended September 30, 2021, respectively. We recognized $0.2 million and $0.7 million of grant funding against research and development expenses for the three and nine months ended September 30, 2020. We recognized $0.4 million and $1.1 million of other income for the three and nine months ended September 30, 2021 that we classified as Australia research and development credit. We recognized $2.6 million of other income for the three and nine months ended September 30, 2020 that we classified as Australia research and development credit.

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 preclinical 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 September 30, 2021 and 2020

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

	Three Months ended September 30,	
	2021	**2020**
	(in thousands)	
Product revenue	$ 63	$ 81
Royalty revenue	47	17
Total revenue	110	98
Operating expenses:		
Cost of revenue	14	-
Research and development	6,146	3,994
General and administrative	4,400	1,795
Total operating expenses	10,560	5,789
Loss from operations	(10.450)	(5,691)
Other income (expenses):		
Interest income (expense)	80	(367)
Loss on extinguishment of convertible notes	-	(540)
Change in fair value of preferred stock warrant liability	-	(5,071)
Change in fair value of derivative liability	-	15
Change in fair value of Clene Nanomedicine contingent earn-out	35,042	-
Change in fair value of Initial Shareholders contingent earn-out	3,439	-
Change in fair value of common stock warrant liability	414	-
Australia research and development credit	364	1,343
Other income, net	(14)	16
Total other income (expense), net	39,325	(4,604)
Net income (loss) before income taxes	28,875	(10,295)
Income tax benefit	69	-
Net income (loss)	28,944	(10,295)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(87)	2
Total other comprehensive income (loss)	(87)	2
Comprehensive income (loss)	$ 28,857	$ (10,293)

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months ended September 30,	
	2021	**2020**
	(in thousands)	
Product revenue	$ 400	$ 160
Royalty revenue	124	17
Total revenue	524	177
Operating expenses:		
Cost of revenue	812	58
Research and development	18,893	10,750
General and administrative	16,739	3,623
Total operating expenses	36,444	14,431
Loss from operations	(35,920)	(14,254)
Other income (expenses):		
Interest expense	(497)	(608)
Gain on extinguishment of notes payable	647	-
Loss on extinguishment of convertible notes	-	(540)
Gain on termination of lease	-	51
Change in fair value of preferred stock warrant liability	-	(7,378)
Change in fair value of derivative liability	-	29
Change in fair value of Clene Nanomedicine contingent earn-out	18,072	-
Change in fair value of Initial Shareholders contingent earn-out	1,710	-
Change in fair value of common stock warrant liability	547	-
Australia research and development credit	1,078	2,611
Other income, net	(13)	34
Total other income (expense), net	21,544	(5,801)
Net loss before income taxes	(14,376)	(20,055)
Income tax benefit	213	-
Net loss	(14,163)	(20,055)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(124)	18
Total other comprehensive income (loss)	(124)	18
Comprehensive loss	$ (14,287)	$ (20,037)

Revenue

We generated revenue of $0.1 million and $0.5 million for the three and nine months ended September 30, 2021. Product revenue of $0.1 million and $0.4 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 $0.1 million and $0.2 million for the three and nine months ended September 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, $47 thousand and $0.1 million of our revenue during the three and nine months ended September 30, 2021 was paid to us by 4Life Research, LLC under an exclusive and royalty-bearing license agreement relating to the sale of KHC46. We generated royalty revenue under the same license agreement of $17 thousand for the three and nine months ended September 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 $14 thousand and $0.8 million for the three and nine months ended September 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 nine months ended September 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) $6.1 million and $4.0 million for the three months ended September 30, 2021 and 2020, respectively, and (ii) $18.9 million and $10.8 million for the nine months ended September 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 nine months ended September 30, 2021 of $2.2 million, or 53.9% and $8.1 million, or 75.7%, 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 months ended September 30, 2021 and 2020, research and development expenses included $0.9 million and $0.1 million, respectively of share-based compensation expense related to stock options and restricted stock awards. During the nine months ended September 30, 2021 and 2020, research and development expenses included $3.9 million and $0.3 million, respectively of share-based compensation expense related to stock options and restricted stock awards.

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) $4.4 million and $1.8 million for the three months ended September 30, 2021 and 2020, respectively, and (ii) $16.7 million and $3.6 million for the nine months ended September 30, 2021 and 2020, respectively. The increases for the three and nine months ended September 30, 2021 of $2.6 million or 145.1% and $13.1 million or 362.0%, respectively, were primarily due to (i) increased professional expenses, public company expenses, legal fees, accounting fees, tax fees, and director and officer insurance expenses 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) $1.6 million and $6.1 million of share-based compensation expense related to stock options and restricted stock awards during the three and nine months ended September 30, 2021.

Other Income (Expenses)

Other income (expenses) consists of interest expense, loss on extinguishment of convertible notes payable, gain on termination of leases, changes in fair value of preferred stock warrant 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, and gain (loss) on extinguishment of notes payable. Other income (expenses), net for the three months ended September 30, 2021 and 2020 included the following:

(i) recognized interest income of $0.1 million and interest expense of $0.4 million, respectively, due to a decrease in the fair value of the 2019 MD Loan and 2019 Cecil Loan, partially offset by the interest on the 2021 Avenue Loan of $0.5 million. As of September 30, 2021, the fair value of notes payable was determined based on the closing price of our Common Stock on Nasdaq of $6.83 per share;

(ii) recognized a loss on extinguishment of convertible notes payable of $0.5 million for the three months ended September 30, 2020;

(iii) recognized expense of $5.1 million relating to the changes in fair value of preferred stock warrant liability for the three months ended September 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;

(iv) recognized income for the change in fair value of the Clene Nanomedicine contingent earn-out liability of $35.0 million for the three months ended September 30, 2021. The change in fair value was primarily a result of the decrease of the closing price of our Common Stock on Nasdaq from $11.24 per share on June 30, 2021 to $6.83 per share on September 30, 2021 when we remeasured the Clene Nanomedicine contingent earn-out liability. There was no Clene Nanomedicine contingent earn-out liability for the three months ended September 30, 2020;

(v) recognized income for the change in fair value of the Initial Shareholders contingent earn-out liability of $3.4 million for the three months ended September 30, 2021. The change in fair value was primarily a result of the decrease of the closing price of our Common Stock on Nasdaq from $11.24 per share on June 30, 2021 to $6.83 per share on September 30, 2021 when we remeasured the Initial Shareholders contingent earn-out liability. There was no Initial Shareholders contingent earn-out liability for the three months ended September 30, 2020;

(vi) 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 September 30, 2021; and

(vii) recognized the change in fair value of the Avenue Warrants of $0.4 million for the three months ended September 30, 2021. The change in fair value was primarily a result of the decrease of the expected term ranging from 3.89 years to 4.56 years on September 30, 2021 from 4.89 years on June 30, 2021, partially offset by the decrease of the closing price of our Common Stock on Nasdaq from $11.24 per share on June 30, 2021 to $6.83 per share on September 30, 2021 when we remeasured the Avenue Warrants. There were no Avenue Warrants for the three months ended September 30, 2020.

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

(i) recognized interest expense of $0.5 million and $0.6 million, respectively, due to a decrease in the fair value of the 2019 MD Loan and 2019 Cecil Loan and the interest expense on the 2021 Avenue Loan of $0.8 million. As of September 30, 2021, the fair value of notes payable was determined based on the closing price of our Common Stock on Nasdaq of $6.83 per share;

(ii) recognized gain on termination of leases of $51 thousand due to the termination of an operating lease for office space for the nine months ended September 30, 2020;

(iii) recognized gain on extinguishment of notes payable of $0.6 million for the nine months ended September 30, 2021, due to the forgiveness of the PPP Note by the U.S. Small Business Administration. We recognized a loss on extinguishment of convertible notes payable of $0.5 million for the nine months ended September 30, 2020;

(iv) recognized expense of $7.4 million relating to the changes in fair value of preferred stock warrant liability for the nine months ended September 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 the Clene Nanomedicine contingent earn-out liability of $18.1 million for the nine months ended September 30, 2021. The change in fair value was primarily a result of the decrease of the closing price of our Common Stock on Nasdaq from $9.01 per share on December 31, 2020 to $6.83 per share on September 30, 2021 when we remeasured the Clene Nanomedicine contingent earn-out liability. There was no Clene Nanomedicine contingent earn-out liability for the nine months ended September 30, 2020;

(vi) recognized income for the change in fair value of the Initial Shareholders contingent earn-out liability of $1.7 million for the nine months ended September 30, 2021. The change in fair value was primarily a result of the decrease of the closing price of our Common Stock on Nasdaq from $9.01 per share on December 31, 2020 to $6.83 per share on September 30, 2021 when we remeasured the Initial Shareholders contingent earn-out liability. There was no Initial Shareholders contingent earn-out liability for the nine months ended September 30, 2020;

(vii) recognized income of $1.1 million and $2.6 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 nine months ended September 30, 2021; and

(vii) recognized the change in fair value of the Avenue warrants of $0.6 million for the nine months ended September 30, 2021. The change in fair value was primarily a result of the decrease of the expected term ranging from 3.89 years to 4.56 years on September 30, 2021 from 5.0 years on May 21, 2021, partially offset by the decrease of the closing price of our Common Stock on Nasdaq from $9.63 per share on May 21, 2021 to $6.83 per share on September 30, 2021 when we remeasured the Avenue Warrants. There were no Avenue Warrants for the nine months ended September 30, 2020.

Comprehensive Income (Loss)

As a result of the foregoing, we (i) generated comprehensive income of $28.9 million and incurred a comprehensive loss of $10.3 million for the three months ended September 30, 2021 and 2020, respectively, and (ii) incurred a comprehensive loss of $14.3 million and $20.0 million for the nine months ended September 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 nine months ended September 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 nine months ended September 30, 2021 and 2020. As of September 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 (“Clene Australia”), 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 nine months ended September 30, 2021 and 2020, respectively. Clene Australia total income tax expense was $0.1 million and $0.2 million for the three and nine months ended September 30, 2021, respectively. During the three and nine months ended September 30, 2020, Clene Australia had no taxable income no provision for income taxes. We recorded $0.4 million and $1.1 million as other income during the three and nine months ended September 30, 2021 for a refund of research and development credits pertaining to Clene Australia for the 2021 tax year. We recorded $2.6 million as other income during the three and nine months ended September 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. (“Clene Netherlands”), 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. During the three and nine months ended September 30, 2021, Clene Netherlands had no taxable income and no provision for income taxes.

JOBS Act

We qualify as an “emerging growth company” as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and may take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements, and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of the initial public offering of Tottenham, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a "large accelerated filer" under the Exchange Act of 1934, which would occur if the market value of the shares of our Common Stock held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter; or (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Smaller Reporting Company Status

We are also a "smaller reporting company" because the market value of our stock held by non-affiliates is less than $700 million as of June 30, 2021 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2020. We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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 a net loss of $14.2 million for the nine months ended September 30, 2021. We incurred net losses of $10.3 million and $20.1 million for the three and nine months ended September 30, 2020. Our loss from operations was $10.5 million and $35.9 million for the three and nine months ended September 30, 2021. Our loss from operations was $5.7 million and $14.3 million for the three and nine months ended September 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 December 2020 PIPE. During the three months ended September 30, 2021, we raised $5.0 million under the 2021 Avenue Loan. During the nine months ended September 30, 2021, we raised $9.3 million from the May 2021 PIPE and $20.0 million under the 2021 Avenue Loan. During the nine months ended September 30, 2020, we raised an aggregate of $41.9 million, consisting of net proceeds from issuance of notes payable, convertible notes payable, and Series D preferred stock.

The net cash used in our operating activities was $25.0 million and $13.1 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had cash and restricted cash of $60.6 million. We expect that the cash on hand as of September 30, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date the condensed consolidated financial statements for the three and nine months ended September 30, 2021 were 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 if 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 the relevant periods:

	Nine Months ended September 30,	
(in thousands)	**2021**	**2020**
Net cash used in operating activities	$ (25,018)	$ (13,121)
Net cash used in investing activities	(661)	(269)
Net cash provided by financing activities	27,130	41,364
Effect of foreign exchange rate changes on cash	(116)	19
Net increase in cash and restricted cash	1,335	27,993

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 $25.0 million of cash for the nine months ended September 30, 2021, which resulted from a net loss of $14.2 million, adjusted for (i) non-cash items of $10.3 million, which primarily consisted of depreciation expense of $0.7 million, non-cash lease expense of $0.1 million, stock-based compensation expense of $9.9 million, changes in fair value of the Clene Nanomedicine contingent earn-out of $18.1 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 $0.5 million, gain on extinguishment of debt of $0.6 million, and increase in interest accrued on notes payable and accretion of debt discount of $0.1 million; and (ii) a net change in operating assets and liabilities of $0.5 million. The net change in operating assets and liabilities was primarily attributable to a decrease in inventory of $0.1 million; an increase in accounts receivable of $48 thousand, an increase in prepaid expenses and other current assets of $1.2 million due to the increase in Australia research and development credit receivable and prepayments to CROs and other vendors, $0.4 million increase in accounts payable, $0.1 million decrease in operating lease obligations, $0.2 million increase in deferred income tax, and $0.5 million increase in accrued liabilities due to the timing of vendor invoicing and payments.

Net cash used in operating activities was $13.1 million of cash for the nine months ended September 30, 2020, which resulted from a net loss of $20.1 million, adjusted for (i) non-cash items of $9.8 million, which primarily consisted of depreciation expense of $0.7 million, stock-based compensation expenses of $0.6 million, changes in the fair value of preferred stock warrant liability of $7.4 million, accretion of debt discount of $0.2 million, loss on extinguishment of convertible notes of $0.5 million, and increase in interest accrued on notes payable of $0.4 million; and (ii) a net change in operating assets and liabilities of $2.8 million. The net change in operating assets and liabilities was primarily attributable to a $2.1 million increase in prepaid expenses and other current assets, $0.3 million decrease in accounts payable, $0.4 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 decrease in payable to related parties.

Investing Activities

Net cash used in investing activities was $0.7 million and $0.3 million for the nine months ended September 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 $27.1 million for the nine months ended September 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 $20.0 million, (iii) proceeds from exercise of stock options of $0.4 million, and (iiii) proceeds from warrants exercised of $10 thousand, partially offset by (i) payments of notes payable issuance costs of $0.5 million, (ii) payments of our finance lease obligations of $0.1 million, (iii) payments of notes payable of $5 thousand, and (iv) payments of deferred transaction costs of $1.9 million.

Net cash provided by financing activities was $41.4 million for the nine months ended September 30, 2020, which primarily resulted from proceeds from the issuance of Series D Preferred Stock of $35.1 million, the issuance of notes payable of $0.7 million and the issuance of convertible notes payable of 6.1 million, partially offset by payments on our finance lease obligations of $0.2 million as well as the deferred offering costs of $0.3 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 2019 MD Loan. Events of default under the 2019 MD Loan include failure to make payments when due, insolvency events, and failure to comply with covenants. We are not in violation of any affirmative 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 2019 MD Loan 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 $0.5 million and $0.3 million were recognized during the three and nine months ended September 30, 2021, respectively. Expense of $0.2 million and $0.3 million was recognized during the three and nine months ended September 30, 2020, respectively. The fair value of $0.8 million and $1.1 million of principal and accrued interest is included in long-term notes payable as of September 30, 2021 and December 31, 2020, respectively.

Cecil County Loan

In April 2019, we entered into a loan agreement (the "2019 Cecil Loan") with Advance Cecil Inc., a non-stock corporation formed under the laws of the State of Maryland with application for 501(c)(3) non-profit status pending before the United States Internal Revenue Service at the time of execution of the 2019 Cecil Loan. 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 covenants to which we will remain subject until maturity. These covenants include providing information about the Company and our operations. There are no financial covenants associated with the 2019 Cecil Loan. Events of default under the 2019 Cecil Loan include failure to make payments when due, insolvency events, and failure to comply with covenants. We are not in violation of any affirmative 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 $0.1 million and $52 thousand were recognized during the three and nine months ended September 30, 2021, respectively. Expense of $42 thousand and $55 thousand was recognized during the three and nine months ended September 30, 2020, respectively. The fair value of $0.2 million and $0.2 million of principal and accrued interest is included in long-term notes payable as of September 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 nine months ended September 30, 2021. There was no gain on extinguishment of debt recorded during the three months ended September 30, 2021.

Avenue Loan

In May 2021, we entered into the 2021 Avenue Loan with Avenue. The agreement provides for a 42-month term loan of up to $30.0 million. The first tranche is $20.0 million ("Tranche 1"), of which $15.0 million was funded at close. We incurred issuance costs for a total of $0.5 million of which $35 thousand has been expensed immediately. The remaining balance from Tranche 1 of $5.0 million was funded on September 28, 2021 and an additional tranche of $10.0 million ("Tranche 2") is available at the Company's request until June 30, 2022. Pursuant to the 2021 Avenue Loan, funding of Tranche 2 is subject to evidence reasonably satisfactory to Avenue 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. On September 27, 2021, we obtained a waiver from this additional financing requirement for the funding of the remaining $5.0 million of Tranche 1 and exercised the option to postpone principal repayment by one year. We incurred additional issuance costs of $75 thousand upon funding the remaining $5.0 million of Tranche 1, of which $12 thousand has been expensed immediately. Funding of Tranche 2 is also subject to (a) 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 the Healey ALS Platform Trial; (ii) REPAIR-PD; or (iii) REPAIR-MS ("Performance Milestone 1"); and (b) 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 loans bear interest at a variable rate per annum equal to the sum of (i) the greater of (A) the prime rate, as published by the Wall Street Journal from time to time or (B) 3.25%, plus (ii) 6.60%. 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 (a) we achieve the First Interest-only Period Extension and (b) have drawn from Tranche 2. On August 16, 2021, we mutually confirmed with Avenue that Performance Milestone 1 and the First Interest-only Period Extension had been achieved. 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 the Avenue Warrants 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 volume weighted average price ("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 Avenue Warrant shall be automatically adjusted to include an additional estimated 86,679 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 and the fair value and issuable shares will be remeasured at each reporting period (see 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, the occurrence of a material adverse change, or defaults in the performance of covenants, insolvency, and bankruptcy. The 2021 Avenue Loan is collateralized by substantially all of our assets other than intellectual property, including capital stock of the Company and its subsidiaries, in which Avenue is granted continuing security interest. 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 nine months ended September 30, 2021, we recorded interest expense of $0.6 million and $0.8 million, respectively.

Contractual Obligations and Commitments

Except as set forth in Note 8, *Notes Payable*, to the 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 September 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 have made an accounting policy election not to recognize leases with an initial term of 12 months or less within our consolidated balance sheet and to recognize those lease payments on a straight-line basis in our consolidated statements of operations and comprehensive income (loss) over the lease term.

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 September 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 September 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 September 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 our appropriate personnel; (b) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized, and implemented appropriately; (c) computer operations controls to ensure that data backups are authorized and monitored; and (d) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

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; and

- 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 September 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; and we continued to engage outside consultants to assist in the design, implementation, and documentation of internal controls that address our relevant risks.

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

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with the other information in this Quarterly Report, including our condensed consolidated financial statements and the related notes appearing in this Quarterly Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our Common Stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Quarterly Report to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, our business, reputation, financial condition, results of operations, revenue and prospects. The material and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially and adversely from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below.

Risk Factors Summary

Our business is subject to numerous material and other risks that you should be aware of before making an investment decision. These risks include, among others, the following:

- We depend substantially on the successful commercialization of our drug candidates in the future, which may fail to materialize or may experience significant delays.
- We currently do not generate any revenue from the commercial sales of drug candidates and we may not become profitable when expected, or at all.
- We have incurred significant net losses since our inception and expect to continue to incur significant net losses for the foreseeable future.
- Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our drug development or commercialization efforts.
- We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- We may encounter difficulties in managing our growth and expanding our operations successfully, which could adversely affect our business, financial condition, results of operations and prospects.
- Changes in government regulation or in practices relating to the pharmaceutical and biotechnology industries, including potential healthcare reform, could decrease the need for our drug candidates, or make it more difficult to obtain regulatory approvals for our drug candidates and commercialize them.
- If we, or any contract research organization ("CRO") we may engage, fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial conditions, results of operations and prospects.
- Our internal computer systems, or those used by any CROs or other third-party contractors or consultants we may engage, may fail or suffer security breaches.
- We manufacture all of our drug candidates ourselves, and intend to manufacture most, if not all, of any approved drugs ourselves as well, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

- Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts, which could harm our business.
- We may fail to get regulatory approval for our products or such approval could be significantly delayed.
- Damage to, destruction of or interruption of production at our manufacturing facilities would negatively affect our business and prospects.
- Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel.

Risks Relating to Our Business and Industry

We depend substantially on the successful commercialization of our drug candidates in the future, which may fail to materialize or may experience significant delays.

As a new biopharmaceutical business, we currently do not have any drugs available for commercial sales nor do we have any drugs that have been approved for sale by the regulatory authorities. We have invested a significant portion of our efforts and financial resources in research and development of our leading drug candidate, CNM-Au8®, a catalytically-active gold nanocrystal suspension, which in early-stage studies has shown potential for the treatment of patients with multiple sclerosis ("MS"), amyotrophic lateral sclerosis ("ALS") and Parkinson's disease ("PD"). Our ability to generate revenue and become profitable in the future depends substantially on the future sales generated by CNM-Au8® and our drug candidates, which in turn depends on the successful research and development ("R&D"), regulatory approval, commercialization and sale of our drug candidates presently under clinical development for the treatment of patients with neurological disorders. We are also developing new drugs based on our technology that have not yet entered into human studies. The ultimate success of our drug candidates is subject to us achieving certain milestones, including without limitation:

- identifying, assessing, acquiring and obtaining evidence of biological activity of new drug candidates to treat certain diseases;
- obtaining satisfactory evidence of safety of these drug candidates in animal toxicology studies;
- obtaining regulatory approval for the conduct of, enrollment in, and completion of, clinical trials of our drug candidates;
- obtaining satisfactory proof of the clinical efficacy and safety of our drug candidates from these clinical trials;
- obtaining approvals and marketing authorizations from regulatory authorities for our drug candidates;
- developing sustainable and scalable manufacturing processes to produce these drug candidates;
- successfully expanding manufacturing processes to support global commercialization capacity of our drug candidates; and
- launching and commercializing any drug candidates for which we may obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor.

If we do not achieve one or more of these milestones in a timely manner, or at all, we could experience significant delays in our ability to obtain approval for and/or to successfully commercialize our drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Even if we are able to generate revenues from any future sales of our drug candidates, we may not become profitable and may need to obtain additional funding to continue operations. Any required funding may not be available on favorable terms or at all. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value significantly and could impair our ability to raise capital, expand our business or continue our operations, which in turn may adversely affect our business, financial condition, and results of operations.

We currently do not generate any revenue from the commercial sales of drug candidates and we may not become profitable when expected, or at all.

Our main business is R&D, and if successful, the sales of drug candidates. As all of our drug candidates are still in the R&D stage, we currently do not generate revenue from the sale of drug candidates, and we have recorded continued significant net losses. We generate an immaterial amount of revenue related to supply agreements for dietary (mineral) supplements and from sales of another product; however, such revenue is not expected to be a material contributor to our revenue in the future. If we fail to commercialize our drug candidates as planned due to failures to complete clinical trials, obtain regulatory approval, conduct commercial scale manufacturing or for any other reason, we may experience significant delays or failure in generating revenue and realizing profit from the commercial sale of our drug candidates.

Further, we expect to incur significant costs in the future, in particular for R&D and the commercialization of our drug candidates. Our R&D expenses were $15.2 million, $9.6 million and $6.6 million in 2020, 2019 and 2018, respectively. For the three and nine months ended September 30, 2021, our R&D expenses were $6.1 million and $18.9 million, respectively. For the three and nine months ended September 30, 2020, our R&D expenses were $4.0 million and $10.8 million, respectively. As drug candidates presently undergoing preclinical research enter into the clinical trial stage, costs associated with such drug candidates may increase significantly. In the future, as we move more drug candidates into the clinical trial stage, conduct more clinical trials for commercialized products to broaden their use, and carry out commercial production of our drug candidates, the costs associated with such operations may increase significantly.

As we operate in the highly competitive pharmaceutical market, we compete to commercialize our drug candidates ahead of our competitors, putting us under pressure to incur R&D and other expenses with a potential negative impact on our profitability. On the other hand, our commercialized drug candidates, if any are approved, may fail to realize their sales potential due to competition, insufficient market demand, product defects, or any other reason. Therefore, even if we ever start to generate revenue from the sales of our commercialized drug candidates in the future, we may still not be profitable for an extended period of time or at all.

We have incurred significant net losses and net operating cash outflows since our inception and expect to continue to incur significant net losses for the foreseeable future.

Investment in biopharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate might fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. We have incurred substantial losses since our inception. During 2020, 2019 and 2018, we recorded a net loss for the year of $19.3 million, $16.2 million and $11.7 million, respectively. We incurred net income of $28.9 million and net loss of $14.2 million for the three and nine months ended September 30, 2021, respectively. We incurred net losses of $10.3 million and $20.1 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021 and December 31, 2020, we had an accumulated deficit of $167.7 million and $153.6 million, respectively. For details, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Substantially all of our operating losses have resulted from costs incurred in connection with our R&D programs and administrative expenses associated with our operations, and we expect that our R&D expenses will continue to increase in the future.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and we continue to build up our commercialization and sales workforce in anticipation of the potential future roll-out of our late-stage drug candidates. Typically, it takes many years to develop one new drug from the drug discovery stage to the time it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development-stage or commercial-stage pharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Our failure to become and remain profitable would decrease our value significantly and impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations.

Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our drug development or commercialization efforts.

As of December 31, 2020, we had cash totaling $59.3 million and an accumulated deficit of $153.6 million. As of September 30, 2021, we had cash and restricted cash totaling $60.6 million and an accumulated deficit of $167.7 million. During the nine months ended September 30, 2021 and 2020, we used net cash in operating activities of $25.0 million and $13.1 million, respectively. We expect to continue to incur losses and use cash in operating activities in 2021 and for the foreseeable future. We expect that the cash on hand as of September 30, 2021 will be sufficient to fund our planned operations for a period extending beyond twelve months from the date of this Quarterly Report. For details, please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.” Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations until our drug candidates begin generating sufficient revenue. 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 R&D programs and commercialization efforts. These factors, among others, may raise substantial doubt about our ability to continue as a going concern.

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a biopharmaceutical company formed in December 2012 focusing on the discovery and development of innovative drugs for the treatment of neurological diseases and other disorders. Our limited operating history, particularly in light of the rapidly evolving nanocrystal therapies field, may make it difficult to evaluate our current business and predict our future performance.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential drug candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. As a relatively new business, we have not yet demonstrated an ability to manufacture drugs at a commercial scale, to arrange for a third party to do so on our behalf, or to conduct sales and marketing activities necessary for successful commercialization. We have not had any product approved for commercial sale and have not generated any revenue from product sales. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, any assessment you make about our current business or future success or viability may not be as accurate as it could be if we had a longer operating history and had been able to reduce some of the uncertainties as set out above. Further, our limited financial track record, without any revenue yet from our expected future principal business, may be of limited reference value for your assessment of our business.

We may encounter difficulties in managing our growth and expanding our operations successfully, which could adversely affect our business, financial condition, results of operations and prospects.

As we seek to advance our drug candidates through clinical trials, we will need to expand our development, regulatory, compliance, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management. Our future financial performance and our ability to commercialize our drug candidates, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional clinical, regulatory, manufacturing, financial, legal, managerial, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successful growth and could harm our business, financial condition, results of operations and prospects.

Changes in government regulation or in practices relating to the pharmaceutical and biotechnology industries, including potential healthcare reform, could decrease the need for our drug candidates, or make it more difficult to obtain regulatory approvals for our drug candidates and commercialize them.

In recent years, the U.S. Congress, the President, executive branch agencies, and state legislatures have considered various types of healthcare reform to control growing healthcare costs. Similar reform movements have occurred in parts of Europe and Asia. Healthcare reform legislation could also increase the costs of drug development and commercialization or limit reimbursement for marketed drugs that could limit the profits to be made from the development of new drugs. This could adversely affect R&D expenditures by pharmaceutical and biotechnology companies, which could in turn decrease the business opportunities available to us in the U.S. and other countries. We are unable to predict what reform proposals will be adopted in the future, if any.

If we, or any CRO we may engage, fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, results of operations and prospects.

We and certain of the third parties we contract with, such as our third-party clinical research organizations (“CROs”), are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. In addition, our future construction projects may necessitate that certain regulatory procedures be completed with the relevant administrative authorities in charge of environmental protection, health and safety before the project can be put into operation. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot entirely eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources.

Although we maintain workers’ compensation insurance to cover the costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, the environmental, health and safety laws and regulations applicable to us and our third-party contractors may change and impose stricter requirements in the future. As a result, we may be required to incur substantial costs to comply with future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our internal computer systems, or those used by any CROs or other third-party contractors or consultants we may engage, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although, to our knowledge, we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions of our systems or those of the vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial-of-service attacks and other malicious activity, as well as security incidents from inadvertent or intentional actions (such as error or theft) by our employees, contractors, consultants, business partners, and/or other third parties, supply chain attacks, power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in our information systems and networks and those of our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We may also be required to comply with laws, regulations, rules, industry standards, and other legal obligations that require us to maintain the security of personal data. We may also have contractual and other legal obligations to notify customers, collaborators, or other relevant stakeholders of security incidents. Failure to prevent or mitigate cyberattacks could result in unauthorized access to data, including proprietary and personal information. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. Such disclosures are costly, could lead to negative publicity, may cause our customer or collaborators or other relevant stakeholders to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security incident. In addition, the costs to respond to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the breach. In addition, our efforts to contain or remediate a security incident or any vulnerability exploited to cause an incident may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, harm to our reputation, and increases to our insurance coverage.

In addition, regulatory response or litigation resulting from security breaches may adversely affect our business. Unauthorized access to our information technology systems could result in litigation with our customers, collaborators, or other relevant stakeholders, or regulatory actions by government entities. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our collaborators were disrupted, we could incur significant liability, which could negatively affect our business and damage our reputation.

Furthermore, our insurance may not be adequate to cover losses associated with such events, and in any case, such insurance may not cover all of the types of costs, expenses, or at all, and losses we could incur to respond to and remediate a security breach. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We manufacture all of our drug candidates ourselves, and intend to manufacture most, if not all, of any approved drugs ourselves as well, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We currently have manufacturing facilities in the U.S. and may build additional manufacturing facilities in other markets to expand our manufacturing capacity. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation, and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources, which may not be available on favorable terms or at all.

Much of the equipment used in our manufacturing process was developed and built by us, and it would be difficult or even impossible to purchase or create suitable replacements in a short period of time. Further, for much of this equipment we have an insufficient amount of or no spare parts available. Were certain equipment, some of which is critical to the production of our drug candidates, to become damaged, lost, or otherwise unusable, we would have to construct new parts, which could take a considerable amount of time, causing a temporary halt to at least a portion of our production operations. Additionally, we are constantly seeking to further fine-tune and develop our advanced manufacturing techniques and process controls to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate, in which case we may lose any competitive advantage.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand, if approved, we will need to increase or "scale up" the production process by a significant factor over current levels of production. A significant part of the scaling up process will include seeking ways to increase the automation and semi-automation of our production process, which will require additional research and development, investment, potential new regulatory approvals, and cooperation with third parties, some of which may not be successful. If we are unable or are delayed in scaling up, or if the cost of doing so is not economically feasible for us, we may not be able to produce our approved drug candidates in a sufficient quantity to meet any future demand.

Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts, which could harm our business.

Our manufacturing facilities will be subject to ongoing, periodic inspection by various regulatory authorities, including the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), China's National Medical Products Administration ("NMPA"), Health Canada, and the Australian Therapeutics Goods Administration ("TGA") or other comparable regulatory agencies to ensure compliance with good manufacturing practices ("GMP"). Our failure to follow and document our adherence to such GMP or other regulatory requirements may lead to significant delays in the availability of products for clinical or, if approved, commercial use, and may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, EMA, NMPA, Health Canada, TGA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with GMP and other requirements of the FDA, EMA, NMPA, Health Canada, TGA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures, or recalls of our drug candidates, operating restrictions and civil or criminal prosecutions, any of which could harm our business.

Damage to, destruction of or interruption of production at our manufacturing facilities would negatively affect our business and prospects.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any of our drugs, if approved, manufactured at that new facility. Such an event could delay our clinical trials or reduce our product sales if any of our drug candidates are approved and successfully commercialized. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition, results of operations and prospects.

Currently, we maintain insurance coverage against damage to our property and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet the requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel.

We are highly dependent on Mark Mortenson, our co-founder and Chief Science Officer, Rob Etherington, our Chief Executive Officer and President, and the other principal members of our management and scientific teams. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of our executive officers, other key employees, and other scientific advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

Recruiting and retaining qualified scientific, technical, clinical, manufacturing, sales, and marketing personnel in the future will also be critical to our success. In addition, we rely on third-party consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development, operations, and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

We benefit from certain tax and financial incentives, the expiration of or changes to which could adversely affect our profitability.

We benefit from certain tax treatments, as well as tax concessions in relation to our research and development costs. We receive refundable tax credits through the R&D tax credits in the United States, Australia, and the state of Maryland. In the United States, the R&D credit is used to offset federal employment taxes on our United States payroll. In Australia, we receive a refundable tax offset of 43.5% of R&D deductions. In Maryland, we receive the Basic Research and Development Tax credit of 3% of the lesser of eligible R&D expenses and the Maryland Base Amount, which is used to offset state income taxes and may be applied against following years' taxes until the credit is used or the credit may be carried forward for seven years. We also receive a tax exemption in Maryland for state personal property and sales tax, as well as the Maryland enterprise zone hiring and job creation tax credits.

In addition, current or future tax treatments, tax concessions, tax allowances and financial incentives applicable to us may be changed, terminated, or otherwise become unavailable due to many factors, including changes in government policy or administrative decisions by the relevant government authorities. Due to potential changes in government policies, we cannot be certain of the level of government grants we will receive in the future. Our post-tax profitability and cash flows may be adversely affected as a result of one or more of these or other factors.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. As of December 31, 2020, we had U.S. federal net operating loss, or NOL, carryforwards of $72.2 million, which may be available to reduce future taxable income and have an indefinite carryforward period but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2020, we had state NOL carryforwards of $59.8 million, which may be available to reduce future taxable income, of which $39.4 million have an indefinite carryforward period while the remaining $20.4 million begin to expire after 2032. As of December 31, 2020, we also had research and development tax credit carryforwards of $1.7 million, which may be available to reduce future tax liabilities and expire at various dates beginning after 2032.

Under U.S. federal tax legislation commonly referred to as the Tax Cuts and Jobs Act ("TCJA"), as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may carry forward indefinitely, but the deductibility of such U.S. federal NOLs incurred in taxable years beginning after December 31, 2020 are limited. It is uncertain how various states will respond to the TCJA and CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Any future offerings of equity securities, together with other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382 of the Code. We have not conducted a study to assess whether any such ownership changes have occurred. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our financial condition and results of operations by effectively increasing our future tax obligations.

Changes in tax laws may adversely affect us, and the Internal Revenue Service or a court may disagree with tax positions taken by us, which may result in adverse effects in our financial condition or the value of our Common Stock.

The TCJA, enacted on December 22, 2017, significantly affected U.S. tax law, including by changing how the United States imposes tax on certain types of income of corporations and by reducing the U.S. federal corporate income tax rate to 21%. It also imposed new limitations on a number of tax benefits, including deductions or business interest, use of net operating loss carry forwards, taxation of foreign income and the foreign tax credit, among others.

The CARES Act, enacted on March 27, 2020, in response to the COVID-19 pandemic, further amended the Internal Revenue Code of 1986 (the "Code"), including in respect of certain changes that were made by the TCJA, generally on a temporary basis. In addition, the Internal Revenue Service ("IRS") has yet to issue guidance on a number of important issues regarding the changes made by the TCJA and the CARES Act. In the absence of such guidance, we will take positions with respect to a number of unsettled issues. There is no assurance that the IRS or a court will agree with the positions taken by us, in which case tax penalties and interest may be imposed that could adversely affect our business, cash flows or financial performance.

Additionally, the current administration may propose significant changes to U.S. tax law, some or all of which may be enacted. The passage of such legislation, as well as changes or modifications in existing judicial decisions or in the current positions of the IRS, could substantially modify the tax treatment described in this Quarterly Report, possibly on a retroactive basis. We cannot predict whether the U.S. Congress or any other legislative body will enact new tax legislation or whether the IRS or any other tax authority will issue new regulations or other guidance, nor can we predict what effect such legislation or regulations might have on us or our financial condition. There can be no assurance that future tax law changes will not increase the rate of the corporate income tax significantly, impose new limitations on deductions, credits or other tax benefits, or make other changes that may adversely affect our business, cash flows or financial performance.

Our financial position and operations may be adversely affected by the COVID-19 pandemic.

An outbreak of the respiratory illness COVID-19 caused by a strain of novel coronavirus, SARS-Cov-2, has spread worldwide, causing many governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restrictions, heightened border scrutiny, and other measures. The outbreak and government measures taken in response to the COVID-19 pandemic have had a significant impact, both direct and indirect, on businesses and commerce. The future progression of the COVID-19 pandemic and its effects on our business and operations are uncertain.

We, our CROs, clinical investigators, third-party vendors and clinical sites may experience disruptions in supply of drug candidates and/or procuring items that are essential for our R&D activities, including raw materials used in the manufacturing of our drug candidates, medical and laboratory supplies used in our clinical trials or preclinical studies or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic. Any disruption in the supply chain from the COVID-19 pandemic, or any potential future outbreak, could have a material adverse effect on our clinical trial plans and business operations.

Additionally, we have enrolled, and will seek to enroll, patients in our clinical trials at sites located in many areas affected by the COVID-19 pandemic and, as a result, our trials have been impacted. In addition, even if sites are actively recruiting, we may face difficulties recruiting or retaining patients in our ongoing and planned clinical trials if patients are affected by the COVID-19 virus or are fearful of visiting or traveling to clinical trial sites because of the COVID-19 pandemic. Prolonged delays or closure to enrollment in our trials or patient discontinuations could have a material adverse impact on our clinical trial plans and timelines.

The response to the COVID-19 pandemic may redirect the Company's resources with respect to regulatory and intellectual property matters in a way that would adversely affect our ability to obtain regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions.

Any negative impact that the COVID-19 pandemic has on the ability of our suppliers to provide materials for our drug candidates or on recruiting or retaining patients in our clinical trials or our ability to collect patient data could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and, if approved, to commercialize our drug candidates, increase our operating expenses, and have a material adverse effect on our financial results.

The COVID-19 pandemic has significantly impacted economies worldwide. The extent to which the COVID-19 pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the COVID-19 pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. The global outbreak of the COVID-19 pandemic continues to evolve and the conduct of our clinical trials may continue to be adversely affected, despite any efforts to mitigate this impact. The COVID-19 pandemic has the potential to adversely affect our business, financial condition, results of operations, and prospects. For details, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Impact of COVID-19 Pandemic."

We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Common Stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Common Stock.

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 in a timely and accurately fashion, 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 that 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: (i) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to our appropriate personnel, (ii) 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, (iii) computer operations controls to ensure that data backups are authorized and monitored, and (iv) 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 a material weakness.

Although we have begun to implement measures to address the material weaknesses, the implementation of these measures may not fully address the material weaknesses and deficiencies in our internal control over financial reporting, and we cannot conclude that these matters have been fully remedied. As we continue to evaluate, and work to improve, our internal control over financial reporting, management may determine that additional or different measures to address control deficiencies or modifications to the remediation plan are necessary. Further, in the future we may determine that we have additional material weaknesses. Our failure to remediate the material weaknesses or failure to identify and address any other material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our Common Stock.

Pursuant to Section 404, after the Reverse Recapitalization, we, as the surviving entity, are required to furnish a report by our management on the effectiveness of our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could adversely affect investor confidence in us and, as a result, the value of our Common Stock.

There is significant uncertainty associated with our drug candidates and their viability as a commercial product.

Metallic nanocrystal therapeutic candidates, such as our lead product, CNM-Au8®, are considered emerging and novel investigational products for the potential treatment of neurological diseases and other disorders. We are developing CNM-Au8® for the treatment of neurological disorders such as MS, ALS, and PD through remyelination and/or neuroprotection mechanisms related to catalysis of certain biological reactions. There are currently no approved remyelination therapies and the evidence for an effect of neuroprotection treatments on these indications is thus far limited. Since there is limited clinical trial data and precedent for the development of nanocrystal therapies that promote remyelination and neuroprotection to treat these indications, there is a substantial risk that the design or outcomes of our clinical trials will not be satisfactory to support regulatory approval. In addition, there are generally limited or no regulatory precedents concerning metallic nanocrystal drug marketing authorization, or a regulatory framework to appropriately differentiate approved nanocrystal product labeling. Our lead metallic nanocrystal drug candidate, CNM-Au8®, contains nanocrystals made entirely of high purity gold alone. It is unclear how regulatory authorities will identify or classify the active moiety of CNM-Au8®, including whether it is classified as a new chemical entity or comparable designation. The inability to obtain sufficiently differentiated active moiety classification from gold generically could potentially limit CNM-Au8® and our drug candidates from ever achieving profitability.

Moreover, the mechanisms of action for nanocrystal therapies are not thoroughly understood, and adverse events or side effects may be observed in clinical trials and reported by medical practitioners in connection with patient usage in the future. If those adverse events or side effects prove significant, they may hamper the ability of our drug candidates to pass through clinical trials or they may outweigh the benefits that patients derive from using our drug candidates, both of which could potentially prevent our drug candidates from ever achieving profitability.

Our drug candidates are not metabolized and may accumulate in the body following long-term usage, making the long-term effects of taking our drug candidates for substantial periods of time uncertain. While all of the current toxicology studies of our drug candidates have resulted in no-adverse-effect levels as of the date of this Quarterly Report, we have not completed reproductive or carcinogenicity studies, which we are required to complete in the future. Any negative results from these studies could materially and adversely affect our business, results of operations, financial condition and prospects.

Moreover, the results of clinical trials for nanocrystal therapies could reveal a high and unacceptable severity and prevalence of undesirable side effects. Any such side effects could adversely impact our ability to obtain regulatory approvals. For example, the FDA, NMPA, Health Canada, TGA, EMA or other comparable authorities could order us to suspend or terminate our studies or to cease further clinical development of or deny approval of our drug candidates. In addition, any adverse drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete trials or may result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

We have not previously obtained any regulatory approval for a drug candidate and we may be unable to obtain or may be delayed in obtaining regulatory approval for any of our drug candidates.

Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without obtaining regulatory approval to market each drug from the FDA, NMPA, Health Canada, TGA, EMA and other comparable regulatory authorities. The time required to obtain approval from regulatory authorities is unpredictable but typically takes years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate’s clinical development and may vary among jurisdictions.

Our drug candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to begin or complete clinical trials due to inability to recruit sufficient numbers of study participants;
- failure to demonstrate that a drug candidate is safe and effective or is safe, pure and potent for our proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;

- regulatory requests for additional analysis, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates;
- insufficient data from the clinical trials of our drug candidates to obtain regulatory approval;
- failure by us or our investigators to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The FDA, NMPA, TGA, Health Canada, EMA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

New or unexpected adverse events, or changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to institutional review boards ("IRBs") or human research ethics committees ("HRECs") for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that product. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

We may not be able to successfully identify, discover, develop or in-license new drug candidates.

We cannot guarantee that we will be successful in identifying potential drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We have devoted significant resources to discovery efforts through our proprietary electro-crystal-chemistry drug development platform, however, we cannot guarantee that we will be successful in identifying additional potential drug candidates, or that we will be able to successfully identify and in-license new drug candidates with high potential from other parties.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial, and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications, and/or drug candidates;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there is no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially and adversely affect our future growth, business, financial condition, results of operations and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

Preclinical and clinical development of drug candidates involves a lengthy and expensive process with an uncertain outcome, and we are unable to predict if or when we will successfully develop or commercialize any of our drug candidates.

There is a risk of failure for each of our drug candidates. Before obtaining regulatory approval for the sale of any of our drug candidates, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or receive regulatory approval. Our internal discovery programs for some of our drug candidates are at an early stage of development and will require significant investment and regulatory approvals prior to commercialization. We are not permitted to market or promote any of our drug candidates until we receive regulatory approval from the FDA, NMPA, TGA, Health Canada, EMA or comparable regulatory authorities, and we may never receive such regulatory approval for any of our drug candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, by the institutional review boards or the ethics committees of the institutions in which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: (1) a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, (2) inspection of the clinical trial operations or trial site by the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, (3) failure to demonstrate a benefit from using a drug, (4) changes in governmental regulations or administrative actions, or (5) lack of adequate funding to continue the clinical trial. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after any regulatory authority has reviewed and commented on the design for our clinical trials.

Preclinical studies and clinical trials are expensive, difficult to design and implement, and can take many years to complete. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analysis, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Future clinical trials of our drug candidates may not be successful.

Commencement of clinical trials is subject to finalizing the trial design based on ongoing discussions with the FDA, NMPA, TGA, Health Canada, EMA and/or other regulatory authorities. The FDA, NMPA, TGA, Health Canada, EMA and other regulatory authorities could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not currently expect. Successful completion of our clinical trials is a prerequisite to submitting a New Drug Application (“NDA”) (or analogous filing) to the FDA, NMPA, TGA, Health Canada, EMA and/or other regulatory authorities for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. We do not know whether the clinical trials for our drug candidates will be completed on schedule, if at all.

Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Future clinical trial results may not be favorable for these and other reasons.

In some cases, there can be significant variability in the safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen, and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical to early- to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates, and/or jeopardize our ability to commence commercialization of our drug candidates.

Clinical trials of our drug candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or may not otherwise produce positive results, which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent us from receiving regulatory approval or commercializing our drug candidates, including:

- regulators, IRBs, or HRECs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our inability to reach agreements on acceptable terms with prospective CROs, clinical trial vendors, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing issues, including problems with manufacturing, supply quality, compliance with GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may not investigate, may not be able to license, or may be unable to properly conduct companion diagnostic tests to identify patients who are likely to benefit from treatment with our drug candidates;

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;

- regulators, IRBs or HRECs may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;

- the cost of clinical trials of our drug candidates may be greater than we anticipate;

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and

- our drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, institutional review boards or ethics committees to suspend or terminate the clinical trials, or reports may arise from preclinical studies or clinical trials of other therapies that raise safety or efficacy concerns about our drug candidates.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our drug candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post-market testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) be unable to obtain reimbursement for use of the drug.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

If we encounter difficulties enrolling patients in clinical trials, clinical trials of our drug candidates may be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until our conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the COVID-19 pandemic;

- the size and nature of the patient population;

- the design of the trial, including the patient eligibility criteria defined in the protocol;

- the size of the study population required for analysis of the trial’s primary endpoints;

- the proximity of patients to trial sites;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- competing clinical trials for similar therapies or other new therapeutics;

- clinicians’ and patients’ perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

Failure of our timely completion of clinical trials would delay the approval and commercialization of our drug candidates, impair the commercial performance of our drug candidates, and consequently harm our business and results of operations.

If we are not able to obtain, or experiences delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the U.S., to the satisfaction of the FDA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA must include significant information regarding the chemistry, manufacturing, and controls for the drug candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. After we submit an NDA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

We have not yet demonstrated an ability to file for or receive regulatory approval for our drug candidates. For example, we do not have experience in preparing the required materials for regulatory submission or navigating the regulatory approval process. As a result, our ability to successfully submit an NDA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

Regulatory authorities outside of the U.S., such as the NMPA, TGA, Health Canada and EMA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation, and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time consuming. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the United States, and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the FDA, NMPA, TGA, Health Canada, EMA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

Favorable designations may not be granted, or if granted, may be withdrawn later, for any of our drug candidates, and may not lead to faster development or regulatory review or approval.

We do not currently have Fast Track Designation or Breakthrough Therapy Designation, but may seek one or more of such designations in the future.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical need for that condition, the drug sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion in deciding whether or not to grant this designation. Even if we believe a particular drug candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a development, review or approval process faster than conventional FDA procedures. The FDA may withdraw a Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain approval from the FDA.

A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our drug candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead decide not to grant that designation. In any event, the receipt of a Breakthrough Therapy Designation for a drug candidate may not result in a faster development, review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as Breakthrough Therapies, the FDA may later decide that such drug candidates no longer meet the conditions for qualification.

Although we have obtained FDA orphan drug designation for CNM-Au8® for the treatment of ALS, we may not realize any benefit from such designation and it does not increase the chance of approval.

The FDA granted orphan drug designation to our lead drug candidate, CNM-Au8®, for the treatment of ALS in May 2019. Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the U.S., or that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that costs of research and development of the product for the indication can be recovered by sales of the product in the U.S. Generally, if a drug with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EMA, from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States and 10 years in the European Union. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Although we have obtained orphan drug designation for CNM-Au8® for the treatment of ALS in the U.S., and may obtain the same designation for other drug candidates or indications, that designation may not effectively protect the drug candidate from competition, if approved, because different drugs can be approved for the same condition and the same drugs can be approved for a different condition but used off-label for any orphan indication we may obtain. Even after an orphan drug is approved, the FDA can subsequently approve a drug that is otherwise the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective, or makes a major contribution to patient care.

Any of our drug candidates, if approved, would continue to be subject to ongoing or additional regulatory obligations and regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

Any of our drug candidates, if approved, will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable regulatory authorities in the European Union, China, Australia and other markets.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, TGA, Health Canada, EMA and other comparable regulatory authority requirements ensuring that quality control and manufacturing procedures conform to GMP. As such, we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA, other marketing applications, and previous responses to any inspection observations if we were to build manufacturing facilities in the future. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the drug candidate. The FDA, NMPA, TGA, Health Canada, EMA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the FDA, NMPA, TGA, Health Canada, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-market information and reports, registration, as well as continued compliance with GMP and GCP, for any clinical trials that we conduct post-approval.

The FDA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, NMPA, TGA, Health Canada, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant penalties and enforcement actions.

Even if we are able to commercialize any approved drug candidates, the drugs may become subject to national or other third-party reimbursement practices or unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. In Europe, Canada, Australia, China, and some markets outside China, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact our revenues.

Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers, and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical, and cost-effectiveness data for the use of our future approved drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drug. Because some of our drug candidates may have a higher cost of goods than conventional small molecule therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot assure that reimbursement will be available for any approved drug candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidate that we commercialize. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, operating results and overall financial condition.

We intend to seek approval alone or in conjunction with partners to market our drug candidates in the U.S., China, the European Union, Australia, Canada, and other jurisdictions. In China, Australia, Canada, and the European Union, the pricing of drugs is subject to governmental control, and it can take considerable time after obtaining marketing regulatory approval to get the future approved drugs reimbursed. Market acceptance and sales of any of our future approved drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs and may be affected by existing and future healthcare reform measures.

Our drug candidates, if approved in the future, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the drug candidate may be smaller than we estimate.

Our drug candidates, if approved in the future, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current MS treatments are well established in the medical community, and physicians may continue to rely on these treatments to the exclusion of our drug candidates that are in clinical trials for the same or similar indications. In addition, physicians, patients, and third-party payors may prefer other novel products to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;
- whether physicians, hospitals, treatment centers and patients consider our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;

- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if any future approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete.

If our drug candidates cause, or are perceived to cause, undesirable side effects, it can result in delays or failure to receive regulatory approval or limitations on the commercial profile of an approved label.

Undesirable side effects caused by our drug candidates could cause either us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities. If the results of the ongoing clinical trials of our drug candidates reveal a high and unacceptable severity and prevalence of undesirable side effects, the clinical trials of our drug candidates could be suspended or terminated and the FDA, NMPA, TGA, Health Canada, EMA or comparable regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and a limited duration of exposure, rare and severe side effects of our drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidates. If our drug candidates receive regulatory approval and we or others discover undesirable side effects caused by such drugs (or any other similar drugs) or that such drug candidates are less effective than previously believed, a number of potentially significant negative consequences could result, including:

- the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities may withdraw or limit their approval of such drug candidates;
- the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contra-indication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of our drug candidates;

- the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities may require the development of risk evaluation and mitigation strategies and plans to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to, or be required to, remove such drug candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drugs; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected drug candidates and could substantially increase the costs of commercializing our drugs, if approved, and significantly impact our ability to successfully commercialize our drugs and generate revenue.

Adverse drug reactions and negative results from off-label use of our products could materially harm our business reputation, product brand name, commercial operations, financial condition, including the value of our Common Stock, and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, patient population, dosage strength or frequency, or other condition of use that is not in accordance with regulatory approved usage and labeling. Even though the FDA, NMPA, TGA, Health Canada, EMA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our products are subject to off-label drug use and are prescribed in a patient population or dosage that has not been approved by competent authorities. Off-label use of our products may be less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations, and financial condition, including the value of our Common Stock. In addition, this may negatively impact our ability to commercialize our products because it could influence third party payers reimbursement and formulary placement decisions about our products. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

Off-label use of our products could expose us to government investigation or prosecution.

Regulatory bodies that enforce laws and regulations to prohibit off-label use may investigate whether our products are being used off-label. Even though we take steps to prevent off-label promotion of our products, this would not necessarily prevent regulatory or prosecuting agencies from investigating and taking action against us as if we were engaged in off-label promotion.

As a company, we have no experience in launching and marketing drugs. If we are unable to develop sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements or arrangements with third parties, we may not be successful in commercializing any drugs, if approved, or generating drug candidate sales revenue.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates, if approved. As a result, our ability to successfully commercialize any approved drugs may involve more inherent risk, take longer, and cost more than it would if we were a company with prior experience launching and marketing drugs.

We will have to compete with other pharmaceutical and biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. We must either develop internal sales, marketing, and commercial distribution capabilities for any or all of our approved drugs or pursue collaborative arrangements regarding the sales and marketing of our approved drugs. However, there can be no assurance that we will be able to develop such distribution capabilities or establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales, if approved, may be lower than if we had commercialized any approved drugs by ourselves or we may fail to generate any product sales revenue in the future at all.

We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of neurological diseases and other disorders for which we are commercializing our drugs or developing our drug candidates. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we may commercialize or may develop. Our competitors may also obtain approval from the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for our drugs, which could result in our competitors establishing a strong market position before we are able to enter the market and/or could slow our regulatory approval.

Many of our current or future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, physician payment transparency laws, privacy and security laws, fraud and abuse laws or similar healthcare and security laws and regulations in the U.S. and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the U.S., our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act and the Civil Monetary Penalties Law, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, also imposes obligations, including mandatory contractual terms, certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare & Medicaid Services ("CMS") information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives. The information reported is publicly available on a searchable website, with disclosure required annually.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or other voluntary industry codes of conduct. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with applicable state law requirements, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government.

Neither the U.S. government nor the U.S. courts have provided definitive guidance on limitations to potential liability under the fraud and abuse laws as they may apply to our business. Law enforcement authorities are increasingly focused on enforcing these laws, often using new and creative legal theories, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Regardless of the compliance efforts, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states. If any such actions are instituted against us, defending against such actions, even if successful, would distract the Company and key personnel from our core mission and impose potentially significant costs. If we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our approved drugs outside the U.S. will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws, as well as the U.S. Foreign Corrupt Practices Act.

If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We may face difficulties from changes to current regulations and future legislation.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell drug candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries are the following: among other things, subjected biological products to potential competition by lower-cost biosimilars, created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Further, the implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from drug candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates.

Any failure to perform proper quality control and quality assurance would have a material adverse effect on our business and financial results.

The manufacturing of our drug candidates and any drugs, if approved, is subject to applicable laws, regulations, and GMP. These regulations govern manufacturing processes and procedures, including record keeping and the implementation and operation of quality management systems to control and assure the quality of investigational products and products approved for sale. We apply stringent quality controls at each stage of our production process to comply with these requirements. We perform extensive tests throughout the manufacturing processes to ensure the safety and effectiveness of our drug candidates. We may, however, detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or the raw material used in our production process was not collected to store in accordance with the GMP or other regulations, resulting in a determination that the implicated products should be destroyed.

In addition, if we fail to comply with relevant quality control requirements under laws, regulations, and GMP, we could experience a disruption in the supply of our products, which could delay or prevent further sales of such products, which could have a material adverse effect on our business and financial results.

In addition, quality issues may arise during scale-up activities. If we are unable to successfully ensure consistent and high quality of our products during large-volume production, the sales of our products may not be able to be promoted, which could have a material adverse effect on our business and financial results.

We may explore the licensing of commercialization rights or other forms of collaboration worldwide, which will expose us to additional risks.

Non-U.S. markets are an important component of our growth strategy. We initially intend to focus on opportunities in the U.S., the European Union, Canada, Australia, Japan, Korea and China, in particular. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these or other markets, or if these arrangements are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing, and distribution efforts may increase our expenses or divert our management's attention from the development of our drug candidates;
- difficulty of effective enforcement of contractual provisions in foreign jurisdictions;
- differing regulatory requirements for drug approvals and marketing internationally, including differing product reimbursement regimes;
- changes in a specific market's political and cultural climate or economic condition;
- potential third-party patent rights or potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation;
- compliance with tax, employment, immigration, and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with Office of Foreign Assets Control rules and regulations and the Foreign Corrupt Practices Act; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes, and fires.

These and other risks may materially and adversely affect our ability to attain or sustain revenue from international markets and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The imports, whether authorized by governmental policy or illegal, of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for any of our future drugs, if approved, and, in turn, may adversely affect our sales and profitability if we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under the current laws of the U.S., China, the European Union, Australia and other jurisdictions. However, illegal imports may continue to occur or even increase as the ability of patients to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our future drugs, if approved, and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower-priced versions of our future drugs, if approved, or competing products from outside the countries where we operate. Any future legislation or regulations that increase consumer access to lower-priced medicines from outside the countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or may be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances to the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future drugs, if approved. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand names. In addition, theft of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, as well as our reputation and business.

We rely on third parties to conduct our preclinical studies and clinical trials and we must work effectively with collaborators to develop our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We rely on and plan to continue to rely on third-party CROs and third-party vendors to monitor, collect samples, analyze samples, report data, and manage data for our ongoing preclinical and clinical programs. We rely on these third parties for execution of our preclinical studies and clinical trials. While we control only certain aspects of their activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs, third-party vendors supporting our clinical programs, and our clinical investigators, are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, NMPA, TGA, Health Canada, EMA, and other comparable regulatory authorities for all of our drugs in clinical development. If we, any of our CROs, third-party vendors, or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA, TGA, Health Canada, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP. Our failure, or the failure of any third party, to comply with these regulations may results in our having to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative CROs, vendors or clinical investigators, or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and other programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and any commercial prospects for our drugs would be harmed, our costs would increase and our ability to generate revenues would be delayed.

Switching or adding additional CROs or clinical investigators involves additional cost and delays, which can materially affect our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter these delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition, results of operations and prospects.

Our ability to generate future revenues is dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them, if approved. We rely on collaborators in various respects, including to undertake research and development programs, to conduct clinical trials, to manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators and we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it would delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators' obligations and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the drug candidates which could materially and adversely affect our business, financial condition, results of operations and prospects.

Our CROs, clinical investigators and third-party vendors may also be impacted by the COVID-19 outbreak. See "—Our financial condition and results of operations may be adversely affected by the COVID-19 pandemic."

We have entered into research collaborations and may form or seek collaborations, joint ventures or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other costs, increase our near and long-term expenditures, disrupt our management and business, or issue securities that dilute our existing shareholders.

While we have entered into collaborative research arrangements with some of the world's leading academic institutions and research centers and are working with key scientists in the field of central nervous system disorders, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, if approved, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than we have, and any agreement that we do enter into may not result in the anticipated benefits.

Further, collaborations involving our drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates, if approved, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors outside of our control, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs;

- collaborators with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly develop, maintain, or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development, or commercialization of our drug candidates, if approved, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of our drug candidates, if approved; and

- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of any current or future research collaborations, strategic partnerships, or the potential licensing of third-party drugs if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of one of more of our drug candidates, reduce or delay our development program or one or more of our future development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or, if approved, bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

Our business depends on the use of raw materials, and a decrease in the supply or an increase in the cost of these raw materials or any quality issues in such raw materials could materially and adversely affect our business, financial condition, results of operations and prospects.

In order to manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. Certain critical raw materials, such as wires made of high-purity gold and other transition elements, are available from a limited number of suppliers in the market. As a result, any disruption in production or inability of our suppliers to produce adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and to continue our research and development of future drug candidates. Moreover, we expect our demand for such materials to increase as we expand our business scale and commercialize our products, if approved, and we cannot guarantee that current suppliers have the capacity to meet our demand. We are also exposed to the risk of increased material costs, which we may not be able to pass on to customers and as a result, we could have lower profitability. In addition, although we have implemented quality inspection procedures on such materials before they are used in our manufacturing processes and also require our suppliers to maintain high quality standards, we cannot guarantee that we will be able to secure sufficient quantities of raw materials at high quality standards, nor detect all quality issues in the supplies we use. For example, should the highly purified water that we utilize be compromised in any way, it could render entire batches unusable or, depending on the nature of the impurity, could be dangerous to patients. Further, we cannot assure you that third parties will be able to maintain and renew all licenses, permits, and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortages of the raw materials utilized by us. If we are unable to obtain adequate raw materials and the quality of our products suffers as a result, we may have to delay clinical trials and regulatory filings, recall our products, be subject to product liability claims, fail to comply with continuing regulatory requirements, and incur significant costs to rectify such issues, which may have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain and maintain sufficient patent protection for our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products similar or identical to our products, and our ability to commercialize our approved drugs successfully may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technology, drug candidates in clinical trials, and approved drugs on market (if approved) from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in most important commercial markets, including the U.S., China, Europe, Canada, Japan, Korea, and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. However, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, China, EPO, and the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

The coverage sought by the claims in a patent application can be significantly reduced before the patent is issued, and the scope of the claims can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to our inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in any country. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (“USPTO”), or become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or approved drugs and compete directly with us without payment, or result in our inability to manufacture or commercialize drug candidates and approved drugs without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords, are limited. For example, approved therapies may face competition from generic medications after the related patents have expired, or if they are challenged and invalidated even before their expiry. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents in court, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in "Business—Intellectual Property" of our Annual Report on Form 10-K filed with the SEC on March 29, 2021. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drugs are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world or prevent unfair competition by third parties.

Filing, prosecuting, maintaining, and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength than do those in the U.S. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing drugs made using our inventions in and into the U.S. or non-U.S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the U.S. These drugs may compete with our future approved drugs and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our drugs could be found invalid or unenforceable if challenged in court or before the U.S. Patent and Trademark Office or comparable non-U.S. authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, protect our trade secrets or determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Enforcement or defense of intellectual property rights can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In patent litigation in the U.S., defendant counterclaims in district courts or in the Patent Trademark and Appeal Board alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of other issued patents belonging to third parties that exist in fields in which we are developing our drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to some aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. We may also have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and increases our operating losses, causing the market price of our Common Stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and most foreign jurisdictions either annually or in several stages over the lifetime of the patent. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If we do not obtain patent term extension and data exclusivity for any drug candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A comparable extension right may exist in other foreign jurisdictions as well. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, no patent term extension system has been established in China beyond the new pilot program, and implementation of the pilot program may not occur quickly. As a result, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

The U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our issued patents and pending patent applications, we rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent the competitor from using that technology or information to compete with us and our competitive position would be harmed.

We may be subject to claims that our employees have wrongfully used or disclosed the alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or may in the future exclusively license;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could prevent the issuance of the patent applications or cause them to be invalidated after issuance;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- we may obtain patents for certain drug candidates many years before we receive NDA approval for these drugs, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, limiting the commercial value of our patents;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; and
- any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Risks Related to the Reverse Recapitalization and Integration of Businesses

We have incurred significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations.

As a newly public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we have faced and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the Public Company Accounting Oversight Board and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements has increased costs and made certain activities more time-consuming. A number of those requirements has required us to carry out activities we have not done previously. Our management and other personnel also have devoted and will continue to devote a substantial amount of time to these compliance initiatives. In addition, additional expenses associated with SEC reporting requirements have been incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It is also more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on the board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations has increased legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs require us to divert a significant amount of money that could otherwise be used to expand our business and achieve strategic objectives. Advocacy efforts by shareholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

We qualify as an emerging growth company and smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our Common Stock less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and may take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of the initial public offering of Tottenham, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a "large accelerated filer" under the Exchange Act, which would occur if the market value of the shares of our Common Stock held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter; or (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

In addition, we are also a "smaller reporting company" because the market value of our stock held by non-affiliates is less than $700 million as of June 30, 2021 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2020. We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We cannot predict if investors will find our Common Stock less attractive because we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

Risks Related to Our Common Stock

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our Common Stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their shares of our Common Stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock. Such provisions include the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of shareholders to change the membership of a majority of our board of directors (the "Board");
- the ability of our Board to approve the issuance shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without shareholder approval, which could be used to significantly dilute the ownership of a hostile acquiror and/or existing stockholders;
- the requirement for the affirmative vote of holders of at least 66⅔% of the voting power of all of the then-outstanding shares of the Common Stock, voting together as a single class, to amend certain provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt;

- the exclusive right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, retirement death, disqualification or removal of a director, which prevents shareholders from being able to fill vacancies on our Board for a period of time; and

- the requirement that a special meeting of shareholders may be called only by our Board, the chairman of our Board or our Chief Executive Officer, which could delay the ability of our shareholders to force consideration of a proposal or to take action, including the removal of directors.

These and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for shareholders or potential acquirors to obtain control of our Board or initiate actions that are opposed by our then-current Board, including the ability to delay or impede a merger, tender offer or proxy contest. The existence of these provisions could negatively affect the price of our Common Stock and limit opportunities for shareholders to realize value in a corporate transaction.

General Risk Factors

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of Common Stock or warrants from trading on its exchange for failure to meet Nasdaq's listing standards, we and our shareholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;

- reduced liquidity for our securities;

- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;

- a limited amount of news and analyst coverage; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

The price of our Common Stock may be volatile.

The stock markets in general and the markets for biotechnology stocks have experienced extreme volatility. The market for the common stock of smaller companies such as ours is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and the share price of our Common Stock is more volatile than the price of the shares of such larger, more established companies and will continue to be for the indefinite future.

The price of our Common Stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we operate;

- variations in our operating performance and the performance of our competitors in general;

- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;

- actual or anticipated fluctuations in our quarterly or annual operating results;

- publication of research reports by securities analysts about us or our competitors or our industry;

- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our Common Stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks, pandemics and acts of war or terrorism.

These market and industry factors may materially reduce the market price of our Common Stock regardless of our operating performance.

Future offerings of debt or equity securities by us may adversely affect the market price of our Common Stock.

In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our Common Stock or offering debt or other equity securities, including commercial paper, medium-term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future clinical trials, commercialization efforts, and acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and/or cash from operations.

Issuing additional shares of our Common Stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing shareholders or reduce the market price of our Common Stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our Common Stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our Common Stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Recent Sales of Unregistered Securities

On July 15, 2021, Chardan exercised a 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. We received no cash proceeds. This issuance was made in reliance upon the exemption to the registration requirements of the Securities Act provided by Rule 506(b) of Regulation D.

(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	Lease Agreement, dated as of August 10, 2021, between Clene Nanomedicine, Inc. and 100 Chesapeake Blvd LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on August 11, 2021).
10.2	Lease Agreement, dated as of August 10, 2021, between Clene Nanomedicine, Inc. and Upper Chesapeake Flex One, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant on August 11, 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).

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: November 8, 2021

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

Dated: November 8, 2021

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

Exhibit 31.1

CERTIFICATION

I, Robert Etherington, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clene Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

/s/ Robert Etherington
Robert Etherington
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Ted (Tae Heum) Jeong, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clene Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

/s/ Ted (Tae Heum) Jeong
Ted (Tae Heum) Jeong
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Robert Etherington, Chief Executive Officer of Clene Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 8, 2021

/s/ Robert Etherington
Robert Etherington
Chief Executive Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Ted (Tae Heum) Jeong, Chief Financial Officer of Clene Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 8, 2021

/s/ Ted (Tae Heum) Jeong
Ted (Tae Heum) Jeong
Chief Financial Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.