

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 March 31, 2021

or

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 01-39834

Clene Inc.

(Exact name of registrant as specified in its charter)

Delaware

85-2828339

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

**6550 South Millrock Drive, Suite G50
Salt Lake City, Utah**

84121

(Address of principal executive offices)

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|--------------------------|--|
| Common stock, \$0.0001 par value | CLNN | The Nasdaq Capital Market |
| Warrants, to acquire one-half of one share of Common Stock for \$11.50 per share | CLNNW | The Nasdaq Capital Market |

Indicate by check mark whether the registrant (1) has filed all reports required by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

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

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

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

The number of shares outstanding of the Registrant's Common Stock as of May 7, 2021 was 59,574,382.

CLENE INC.
Quarterly Report on Form 10-Q for the Period Ended March 31, 2021

| | |
|--|----|
| <u>PART I – FINANCIAL INFORMATION</u> | 1 |
| <u>ITEM 1. UNAUDITED FINANCIAL STATEMENTS</u> | 2 |
| <u>CONDENSED CONSOLIDATED BALANCE SHEETS</u> | 2 |
| <u>CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS</u> | 3 |
| <u>CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)</u> | 4 |
| <u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u> | 5 |
| <u>NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u> | 6 |
| <u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u> | 31 |
| <u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u> | 45 |
| <u>ITEM 4. CONTROLS AND PROCEDURES</u> | 45 |
| <u>PART II – OTHER INFORMATION</u> | 47 |
| <u>ITEM 1. LEGAL PROCEEDINGS</u> | 47 |
| <u>ITEM 1A. RISK FACTORS</u> | 47 |
| <u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u> | 47 |
| <u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u> | 47 |
| <u>ITEM 4. MINE SAFETY DISCLOSURES</u> | 47 |
| <u>ITEM 5. OTHER INFORMATION</u> | 47 |
| <u>ITEM 6. EXHIBITS</u> | 48 |
| <u>SIGNATURES</u> | 49 |

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)

| | <u>March 31,</u> <u>2021</u> | <u>December 31,</u> <u>2020</u> |
|--|---------------------------------|------------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash | \$ 48,041 | \$ 59,275 |
| Accounts receivable | 123 | 21 |
| Inventory | 355 | 191 |
| Prepaid expenses and other current assets | 4,824 | 3,502 |
| Total current assets | <u>53,343</u> | <u>62,989</u> |
| Right-of-use assets | 1,006 | 1,029 |
| Property and equipment, net | 4,182 | 4,225 |
| TOTAL ASSETS | <u><u>\$ 58,531</u></u> | <u><u>\$ 68,243</u></u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current liabilities: | | |
| Accounts payable | \$ 739 | \$ 1,124 |
| Accrued liabilities | 2,730 | 3,960 |
| Income tax payable | 164 | 164 |
| Deferred revenue from related parties | 112 | 112 |
| Operating lease obligations, current portion | 202 | 194 |
| Finance lease obligations, current portion | 139 | 190 |
| Clene Nanomedicine contingent earn-out, current portion | - | 5,924 |
| Total current liabilities | <u>4,086</u> | <u>11,668</u> |
| Operating lease obligations, net of current portion | 1,723 | 1,785 |
| Finance lease obligations, net of current portion | 210 | 205 |
| Notes payable | 1,844 | 1,949 |
| Deferred income tax | 214 | 260 |
| Clene Nanomedicine contingent earn-out, net of current portion | 77,663 | 46,129 |
| Initial Shareholders contingent earn-out | 8,867 | 5,906 |
| TOTAL LIABILITIES | <u>94,607</u> | <u>67,902</u> |
| Stockholders' equity (deficit): | | |
| Common stock, \$0.0001 par value: 100,000,000 shares authorized; 59,574,382 and 59,526,171 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively | 6 | 6 |
| Additional paid-in capital | 156,886 | 153,571 |
| Accumulated deficit | (193,317) | (153,561) |
| Accumulated other comprehensive income | 349 | 325 |
| TOTAL STOCKHOLDERS' EQUITY (DEFICIT) | <u>(36,076)</u> | <u>341</u> |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | <u><u>\$ 58,531</u></u> | <u><u>\$ 68,243</u></u> |

See accompanying notes to the condensed consolidated financial statements.

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

| | Three Months Ended March 31, | |
|--|---------------------------------|-------------------|
| | 2021 | 2020 |
| Revenue: | | |
| Product revenue | \$ 199 | \$ 70 |
| Royalty revenue | 14 | - |
| Total revenue | <u>213</u> | <u>70</u> |
| Operating expenses: | | |
| Cost of revenue | 243 | 58 |
| Research and development | 6,275 | 3,202 |
| General and administrative | 5,390 | 812 |
| Total operating expenses | <u>11,908</u> | <u>4,072</u> |
| Loss from operations | (11,695) | (4,002) |
| Other income (expense), net: | | |
| Interest expense | (551) | (51) |
| Gain on extinguishment of notes payable | 647 | - |
| Change in fair value of preferred stock warrant liability | - | 112 |
| Change in fair value of derivative liability | - | 4 |
| Change in fair value of Clene Nanomedicine contingent earn-out | (25,610) | - |
| Change in fair value of Initial Shareholders contingent earn-out | (2,961) | - |
| Australia research and development credit | 339 | - |
| Other income (expense), net | 3 | (4) |
| Total other income (expense), net | <u>(28,133)</u> | <u>61</u> |
| Net loss before income taxes | (39,828) | (3,941) |
| Income tax benefit | 72 | - |
| Net loss | (39,756) | (3,941) |
| Other comprehensive income: | | |
| Foreign currency translation adjustments | 24 | 6 |
| Total other comprehensive income | <u>24</u> | <u>6</u> |
| Comprehensive loss | <u>\$ (39,732)</u> | <u>\$ (3,935)</u> |
| Net loss per share-- basic and diluted (Note 19) ⁽¹⁾ | <u>(0.66)</u> | <u>(0.23)</u> |
| Weighted average common shares used to compute basic and diluted net loss per share ⁽¹⁾ | <u>60,670,932</u> | <u>17,357,505</u> |

(1) Retroactively restated for the three months ended March 31, 2020 for the Reverse Recapitalization as described in Note 1

See accompanying notes to the condensed consolidated financial statements.

CLENE INC.

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

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

(Unaudited)

| | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders' Equity (Deficit) |
|--|--|-----------|--------------|--------|----------------------------------|------------------------|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| Balances at December 31, 2020 | - | \$ - | 59,526,171 | \$ 6 | \$ 153,571 | \$ (153,561) | \$ 325 | \$ 341 |
| Exercise of stock options | | | 48,211 | - | 50 | - | - | 50 |
| Stock-based compensation expense | - | - | - | - | 3,265 | - | - | 3,265 |
| Foreign currency translation adjustment | - | - | - | - | - | - | 24 | 24 |
| Net loss | - | - | - | - | - | (39,756) | - | (39,756) |
| Balances at March 31, 2021 | - | \$ - | 59,574,382 | \$ 6 | \$ 156,886 | \$ (193,317) | \$ 349 | \$ (36,076) |
| Balances at December 31, 2019 | 27,499,837 | \$ 72,661 | 17,357,505 | \$ 2 | \$ 1,754 | \$ (69,571) | \$ 41 | \$ (67,774) |
| Stock-based compensation expense | - | - | - | - | 171 | - | - | 171 |
| Foreign currency translation adjustment | - | - | - | - | - | - | 6 | 6 |
| Net loss | - | - | - | - | - | (3,941) | - | (3,941) |
| Balances at March 31, 2020 | 27,499,837 | \$ 72,661 | 17,357,505 | \$ 2 | \$ 1,925 | \$ (73,512) | \$ 47 | \$ (71,538) |

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

See accompanying notes to the condensed consolidated financial statements.

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

| | Three Months Ended | |
|---|---------------------------|-----------------|
| | March 31, | |
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Net loss | \$ (39,756) | \$ (3,941) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 244 | 218 |
| Non-cash lease expense | 22 | 40 |
| Change in fair value of preferred stock warrant liability | - | (112) |
| Change in fair value of Clene Nanomedicine contingent earn-out | 25,610 | - |
| Change in fair value of Initial Shareholders contingent earn-out | 2,961 | - |
| Stock-based compensation expense | 3,265 | 171 |
| Change in fair value of derivative | - | (4) |
| Gain on extinguishment of debt | (647) | - |
| Accretion of debt discount | - | 20 |
| Increase in interest accrued on notes payable | 543 | 20 |
| Changes in operating assets and liabilities: | | |
| Inventory | (164) | - |
| Accounts receivable | (103) | (70) |
| Prepaid expenses and other current assets | (1,321) | (91) |
| Accounts payable | 161 | 604 |
| Accrued liabilities | 125 | (79) |
| Deferred income tax | (46) | - |
| Operating lease obligations | (55) | (27) |
| Net cash used in operating activities | <u>(9,161)</u> | <u>(3,251)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (203) | (23) |
| Net cash used in investing activities | <u>(203)</u> | <u>(23)</u> |
| Cash flows from financing activities: | | |
| Proceeds from exercise of stock options | 50 | - |
| Payments of deferred offering costs | (1,901) | - |
| Payments of finance lease obligations | (45) | (53) |
| Proceeds from the issuance of note payable | - | 1,600 |
| Net cash provided by (used in) financing activities | <u>(1,896)</u> | <u>1,547</u> |
| Effect of foreign exchange rate changes on cash | 26 | 55 |
| Net decrease in cash | (11,234) | (1,672) |
| Cash – beginning of period | <u>59,275</u> | <u>8,788</u> |
| Cash – end of period | <u>\$ 48,041</u> | <u>\$ 7,116</u> |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Issuance of derivative instrument related to convertible notes | \$ - | \$ 197 |
| Supplemental disclosure: | | |
| Cash paid for interest expense | \$ 8 | \$ 11 |

See accompanying notes to the condensed consolidated financial statements.

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

1. Nature of the Business

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

The accompanying condensed consolidated financial statements include the accounts of the Company and its 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 subsequent to the quarter ended March 31, 2021 and has no financial positions or operations and therefore is not included in the condensed consolidated financial statements.

Reverse Recapitalization with Tottenham Acquisition 1 Limited

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 Acquisition I Limited (“**Tottenham**” or “**TOTA**”), Chelsea Worldwide Inc., a Delaware corporation and wholly-owned subsidiary of Tottenham (“**PubCo**”), Creative Worldwide Inc., a Delaware corporation and wholly owned subsidiary of PubCo (“**Merger Sub**”), and Fortis Advisors LLC, a Delaware limited liability company as the representative of the Company’s stockholders (“**Stockholders’ Representative**”). Prior to the Reincorporation Merger discussed below, Tottenham was incorporated in the British Virgin Islands as a blank check company for the purpose of entering into a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combination with one or more businesses or entities.

The Reverse Recapitalization was effected in two steps: (i) Tottenham was reincorporated to the state of Delaware by merging with and into PubCo (the “**Reincorporation Merger**”); (ii) promptly following the Reincorporation Merger, Merger Sub was merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine becoming a wholly-owned subsidiary of PubCo (the “**Acquisition Merger**”). On the Closing Date, PubCo changed its name from Chelsea Worldwide Inc. to Clene Inc. and listed its shares of common stock, par value \$0.0001 per share (“**Common Stock**”) on the Nasdaq Stock Exchange (the “**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 (excluding certain shares to be canceled pursuant to the Merger Agreement, any redeemed shares and any dissenting), was automatically cancelled and cease to exist and (i) for each Tottenham ordinary share, the Company issued to each shareholder one validly-issued share of the Company’s Common Stock; (ii) each warrant to purchase one half (1/2) of one Tottenham Ordinary Share converted into a warrant to purchase one-half of one share of the Company’s 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 the Company’s Common Stock; provided, however, that no fractional shares were issued and all fractional shares were rounded down to the nearest whole share.

On the Closing Date, each share of Clene Nanomedicine common stock was cancelled and the holders thereof in exchange received 0.1389 newly-issued shares of Clene Inc. Common Stock, which is the exchange ratio (the “**Exchange Ratio**”). Pursuant to the Merger Agreement, 5% of the aggregate amount of the closing payment shares, or 2,716,958 shares will be held in escrow to satisfy any indemnification obligation incurred and will be 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 the Company’s 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 the Company Common Stock with the same terms and conditions except adjusted by the aforementioned Exchange Ratio. 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 the Company’s Common Stock, which is 95% of the Exchange Ratio. Pursuant to the Merger Agreement, the Company issued 370,101 of restricted stock units (“**RSUs**”) to the option holders which complements the 5% closing payment shares held in escrow for Clene Nanomedicine common shareholders. The modification of the stock options did not result in a material incremental compensation expense upon closing of the Reverse Recapitalization.

In addition, the Company issued 1,136,961 RSUs to option holders to complement the earn-out payments that would contingently be issued to certain current Clene Nanomedicine’s shareholders upon the achievement of milestones. See Note 3 for the milestones detail.

The proceeds received from the Reverse Recapitalization is \$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 \$10.00 per unit. Each of the units consists of one and one-tenth shares of Tottenham’s ordinary shares for \$10.00 per share 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 five years after the consummation of the Reverse Recapitalization (i.e., December 30, 2025) (see Note 10).

Also, in connection with the Reverse Recapitalization, 644,164 shares of the Company’s Common Stock were issued to LifeSci Capital LLC (“**LifeSci**”), as payment for advisory services rendered in connection with the Reverse Recapitalization (see Notes 3 and 18).

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 is primarily based on the fact that subsequent to the Reverse Recapitalization, Clene Nanomedicine’s stockholders have a majority of the voting power of the combined company, Clene Nanomedicine comprises all of the ongoing operations of the combined entity, Clene Nanomedicine comprises a majority of the governing body of the combined company, and Clene Nanomedicine’s senior management comprises all of the senior management of the combined company. Accordingly, for accounting purposes, this transaction was treated as the equivalent of Clene Nanomedicine issuing shares for the net assets of Tottenham, accompanied by a recapitalization. The shares and net loss per common share, prior to the Reverse Recapitalization, have been retroactively restated as shares reflecting the Exchange Ratio established in the Reverse Recapitalization (0.1389 Clene Inc. shares for 1 Clene Nanomedicine share). 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.

The PIPE Offering

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 the Company’s Common Stock (the “**PIPE Shares**”) at a price of \$10.00 per share with net proceeds of \$22.2 million. The purpose of the PIPE is to fund general corporate expenses. In addition, investors in the PIPE offering also received warrants to purchase a number of shares equal to one-half (1/2) of the number of PIPE Shares, totaling 1,119,750 shares of the Company’s Common Stock, at an exercise price of \$0.01 per share for each of the PIPE Shares (the “**PIPE Warrants**”), subject to a 180-day holding period.

See Note 3 – Reverse Recapitalization with Tottenham and Clene Nanomedicine for additional details on Reverse Recapitalization.

Registration Statement

We filed a registration statement on Form S-1 (file number 333-253173) to register 4,541,481 shares of Common Stock underlying outstanding warrants that we have previously issued, among which 2,517,500 and 904,231 warrants were originally issued by Tottenham and Clene Nanomedicine, respectively, prior to the closing of the Reverse Recapitalization, and 1,119,750 warrants were issued as part of the PIPE offering 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 \$27 thousand of certain offering costs during the three months ended March 31, 2021 recognized as expense within general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss during the three months ended March 31, 2021.

Accounting for Warrants Issued by SPACs

On April 12, 2021, the Staff of the SEC (the “Staff”) released the Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (“SPACs”) (the “Statement”). The Statement provides additional information regarding the Staff’s views about equity treatment for SPAC-issued warrants, suggesting that certain nearly ubiquitous features in SPAC warrants require the warrants to be classified as liabilities on the SPAC’s balance sheet rather than as equity. It also highlights financial reporting considerations if a SPAC determines it has misclassified its warrants. As a result of the Statement, the Company re-evaluated the accounting for TOTA’s Public Warrants, Private Warrants, and Chardan Unit Purchase Option Warrants as of the date of their issuance in August 2018 and has concluded that they were appropriately classified as equity. The provisions highlighted in the Statement as potentially requiring liability classification are not featured in the Warrant Agreement and in the Chardan Unit Purchase Option Agreement, and the terms of the warrants do not preclude them from being considered indexed to the entity’s own stock and classified as equity.

Liquidity

We have incurred significant losses and negative cash flows from operations since our inception. We incurred net losses of \$39.8 million and \$3.9 million for the three months ended March 31, 2021 and 2020. As of March 31, 2021, our cash totaled \$48.0 million, and our accumulated deficit was \$193.3 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 \$9.2 million and \$3.3 million for the three months ended March 31, 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. 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 March 31, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date these condensed consolidated financial statements are issued.

Impact of the COVID-19 Coronavirus Pandemic

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the pandemic and its effects on our business and operations 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, the Company and our clinical research organizations (“CROs”) may face disruptions that may affect our ability to initiate and complete preclinical studies, manufacturing disruptions, and delays at clinical trial sites. The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds to support our operations. Moreover, the pandemic has significantly impacted economies worldwide and could result in adverse effects on our business and operations.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

We have prepared the accompanying condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial reporting and as required by Regulation S-X, Rule 10-01. The condensed consolidated financial statements have been prepared on the same basis as our audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of our financial position as of March 31, 2021 and the results of our operations and our cash flows for the three months ended March 31, 2021 and 2020 and the condensed consolidated statement of stockholders’ equity (deficit) as of March 31, 2021 and 2020. The financial data and other information disclosed in these notes related to the three months ended March 31, 2021 and 2020 are unaudited. The results of operations for the three months ended March 31, 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, and Preferred 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 are recorded in the period in which they become known.

Risks and Uncertainties

The product candidates we develop require approvals from the U.S. Food and Drug Administration (“FDA”) or foreign regulatory agencies prior to commercial sales. There can be no assurance that our current and future product candidates will receive the necessary approvals or be commercially successful. If we are denied approval or approval is delayed, it will have a material adverse impact on our business and our condensed consolidated financial statements.

We are subject to risks common to companies in the development stage including, but not limited to, dependency on the need for substantial additional financing to achieve our goals, uncertainty of broad adoption of our approved products, if any, by physicians and patients, significant competition, and untested manufacturing capabilities.

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future 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 March 31, 2021 and December 31, 2020, we had no cash equivalents and no restricted cash balances.

Derivative Instruments

The convertible promissory notes issued in February through July 2020 (“**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**”). The 2020 Derivative Instrument was recorded at fair value at inception and was subject to re-measurement to fair value at each balance sheet date and immediately prior to the extinguishment of derivative liability, with any changes in fair value recognized in the condensed consolidated statements of operations and comprehensive loss. 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 convertible promissory notes was automatically converted into shares of Series D Preferred Stock and the derivative liability was extinguished (see Notes 11 and 12).

Contingent Earn-out

In connection with the Reverse Recapitalization and pursuant to the Merger Agreement, Clene Nanomedicine’s common shareholders and Initial Shareholders of Tottenham are entitled to receive additional shares of our Common Stock (the “**Contingent Earn-outs**”) upon us achieving certain milestones described in Note 3 and 12. In accordance with ASC 815 – *Derivatives and hedging*, the Contingent Earn-out shares are not indexed to our own stock and therefore are accounted for as a liability at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

The estimated fair value of the Contingent Earn-out shares for Clene Nanomedicine’s common shareholders (the “**Clene Nanomedicine Contingent Earn-out**”) and the Contingent Earn-out shares for the Initial Shareholders of Tottenham (the “**Initial Shareholders Contingent Earn-out**”) were determined using a Monte Carlo simulation that simulated the future path of our Common Stock price over the earn-out periods. The assumptions utilized in the calculation are based on the achievement of certain stock price milestones including projected stock price, volatility, and risk-free rate. For potential payments related to a product development milestone, the fair value was determined based on our expectations of achieving such a milestone and the simulated estimated stock price on the expected date of achievement.

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

Preferred Stock Warrant Liability

Prior to the Reverse Recapitalization with Tottenham, we accounted for freestanding warrants to purchase shares of Preferred Stock as liabilities on the balance sheet at their estimated fair value as the underlying redeemable convertible Preferred Stock was considered contingently redeemable and may obligate us to transfer assets to the holders at a future date upon the occurrence of a deemed liquidation event. At the end of each reporting period, changes in the estimated fair value of the warrants to purchase shares of Preferred Stock were recorded in change in fair value of Preferred Stock warrant liability in the condensed consolidated statements of operations and comprehensive loss. The change in the estimated fair value of the Preferred Stock warrant liability was \$0.1 million for the three months ended March 31, 2020. In connection with the Reverse Recapitalization, all Clene Nanomedicine Preferred Stock was converted to the Clene Inc. Common Stock and the Clene Nanomedicine Preferred Stock warrants were converted to warrants to purchase Clene Inc. Common Stock. We assessed the features of these warrants and determined that they qualify for classification as permanent equity. Accordingly, we remeasured the warrants to fair value upon the closing of the Reverse Recapitalization and reclassified the resulting warrant liability to additional paid-in capital (See Note 16).

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, *Distinguishing Liabilities from Equity* (“ASC 480”) and ASC 815, *Derivatives and Hedging* (“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 the Company’s own 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 as of each subsequent quarterly period end date while the warrants are outstanding (See Note 10).

Grant Funding

We may submit applications to receive grant funding from governmental and non-governmental entities. Grant funding received that involves no conditions or continuing performance obligations of the Company is recognized upon receipt. Grant funding with conditions or obligations of the Company is recognized as the conditions or obligations are fulfilled. We have made an accounting policy election to record such unconditional grants, such as the Australian Research and Development Credit, as other income in the condensed consolidated statements of operations and comprehensive loss. Income from grants is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants were provided have been met. We recognize the Australian Research and Development Credit in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. During the three months ended March 31, 2021 and 2020, we recognized \$0.3 million and \$0, respectively, of Australian Research and Development Credit within other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2021, and December 31, 2020, we recorded \$2.4 million and \$2.1, 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 in the condensed consolidated balance sheets if the conditions or obligations are expected to be met within the next twelve months. As of March 31, 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 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 months ended March 31, 2021, we recorded a grant of \$0.5 million from the Michael J. Fox Foundation as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive loss. We did not record any grants for the three months ended March 31, 2020.

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. There were no transfers between the levels in the fair value hierarchy during the three months ended March 31, 2021 and 2020.

See Note 16 for information on our liabilities measured at fair value as of March 31, 2021 and December 31, 2020.

Comprehensive Loss

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

Recently Adopted Accounting Pronouncements

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

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

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The amendments in this ASU, among other things, require the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Financial institutions and other organizations will now use forward-looking information to better inform their credit loss estimates. The guidance is effective for fiscal years beginning after December 15, 2022. We are currently evaluating the expected impact of the new guidance as a result of this extended deadline of implementation for smaller reporting companies.

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

3. Reverse Recapitalization with Tottenham and Clene Nanomedicine

On December 30, 2020, the Company consummated the Reverse Recapitalization, pursuant to which Tottenham merged with and into PubCo in connection with the Reincorporation Merger and PubCo merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine becoming a wholly-owned subsidiary of PubCo. On the Closing Date, PubCo changed its name from Chelsea Worldwide, Inc. to Clene Inc. (see Note 1).

Upon the consummation of the Reverse Recapitalization, each Tottenham ordinary share issued and outstanding immediately prior to the effective time of the Reincorporation Merger was automatically cancelled and ceased to exist and (i) for each Tottenham ordinary share, the Company issued one validly-issued share of the Company's Common Stock; (ii) each warrant to purchase one half of one Tottenham Ordinary Share was converted into a warrant to purchase one-half of one share of the Company's Common Stock; and (iii) each Tottenham right exchangeable into one-tenth (1/10) of one Tottenham ordinary share was converted into a right exchangeable for one-tenth (1/10) of one share of the Company's Common Stock. As a result of the Reverse Recapitalization, all outstanding shares of Tottenham ordinary shares of 2,303,495 held by the Initial Shareholders and Tottenham public shareholders were converted into the same number of the Company's Common Stock. In addition, pursuant to the Merger Agreement, the Initial Shareholders are entitled to receive up to 750,000 of the Company's Common Stock as earn-out shares upon the achievement of certain milestones described below. The Initial Shareholders Contingent Earn-out is accounted for as a contingent liability on the condensed consolidated balance sheets.

In accordance with the Merger Agreement, on the closing of the Reverse Recapitalization, each share of Clene Nanomedicine preferred stock and common stock then issued and outstanding was automatically cancelled, extinguished and exchanged for 0.1389 newly-issued shares of Clene Inc. Common Stock. 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 Clene Inc. Common Stock are to be issued and held in escrow to satisfy any indemnification obligations incurred under the Merger Agreement. In addition, all outstanding warrants (other than warrants that expired, were exercised or were deemed automatically net exercised immediately prior to the Acquisition Merger) exercisable for common stock in Clene Nanomedicine were assumed by the Company with no changes to the terms and conditions of the warrants. The warrants have been retroactively restated to reflect the Exchange Ratio established in the Reverse Recapitalization.

In connection with the Reverse Recapitalization, a total of 53,286,115 stock options of Clene Nanomedicine common stock were cancelled and the holders thereof in exchange received 0.1320 newly-issued stock options of Clene Inc. Common Stock for a total of 7,032,591 shares, which is 95% of the Exchange Ratio. Pursuant to the Merger Agreement, the Company issued RSUs to the option holders which complements the 5% closing payment shares held in escrow for Clene Nanomedicine common shareholders. In addition, the Company issued 1,136,961 RSUs to option holders to complement the earn-out payments that would be contingently issued to certain current Clene Nanomedicine shareholders upon the achievement of milestones described below.

Also, in connection with the Reverse Recapitalization, Clene Nanomedicine entered into a letter agreement with 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 the Company's 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).

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, the Company paid \$2.1 million to Chardan as settlement of the deferred underwriting fees which amount was included in the total offering costs of the Reverse Recapitalization transaction.

During the year ended December 31, 2020, the Company 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 the Company's condensed consolidated balance sheets.

On December 28, 2020 and prior to the close of the Reverse Recapitalization on December 30, 2020, various PIPE investors purchased 2,239,500 shares of the Company's Common Stock at a price of \$10.00 per share and 1,119,750 warrants to purchase one share of the Company's Common Stock at an exercise price of \$0.01 per share, for net proceeds of \$22.2 million (see Notes 10 and 18).

Earn-out Shares

Certain of Clene Nanomedicine's current stockholders are entitled to receive earn-out shares as follows (the "**Clene Nanomedicine Contingent Earn-out**"): (i) 3,333,333 shares of the Company's Common Stock if (A) the volume-weighted average price ("**VWAP**") of the shares of the Company's 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 the Company's 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 the Company's Common Stock if (A) the VWAP of the shares of the Company's 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 the Company's 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 the Company's 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 stockholders 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 the Company's 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 the Company's 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-out**") 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 will be subsequently remeasured to fair value at each reporting date (see Note 16).

As a result of the Reverse Recapitalization and the PIPE offering, Clene Nanomedicine's stockholders own approximately 91% of the Common Stock of the Company, Tottenham public stockholders own approximately 4% of the Common Stock of the Company, and investors from the PIPE own approximately 4% of the Common Stock of the Company, based on the number of shares of Clene Inc. Common Stock outstanding on December 30, 2020 (in each case, not giving effect to any shares issuable upon exercise of Clene Inc. warrants, options, or earn-out shares).

4. Prepaid expenses and other current assets

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

| (in thousands) | March 31, 2021 | December 31, 2020 |
|--|---------------------------|------------------------------|
| Australia research and development credit receivable | \$ 2,409 | \$ 2,148 |
| CRO prepayments | 850 | 1,211 |
| Metals to be used in research and development | 486 | 31 |
| Directors & Officers Insurance | 882 | - |
| Other | 197 | 112 |
| | <u>\$ 4,824</u> | <u>\$ 3,502</u> |

5. Property and Equipment, Net

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

| (in thousands) | March 31, 2021 | December 31, 2020 |
|-----------------------------------|---------------------------|------------------------------|
| Lab equipment | \$ 3,068 | \$ 3,077 |
| Furniture and fixtures | 147 | 147 |
| Leasehold improvements | 3,927 | 3,889 |
| Construction in progress | 663 | 490 |
| | <u>7,805</u> | <u>7,603</u> |
| Less accumulated depreciation | (3,623) | (3,378) |
| Total property and equipment, net | <u>\$ 4,182</u> | <u>\$ 4,225</u> |

Depreciation expense related to property and equipment, net for the three months ended March 31, 2021 and 2020 was approximately \$0.2 million and \$0.2 million, respectively. Depreciation expense is reported in research and development expense and in general and administrative expense for \$0.2 million and \$1 thousand, respectively, in the condensed consolidated statements of operations and comprehensive loss.

6. Accrued Liabilities

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

| (in thousands) | March 31, 2021 | December 31, 2020 |
|-----------------------------------|-------------------|----------------------|
| Accrued professional fees | \$ - | \$ 189 |
| Accrued compensation and benefits | 1,316 | 1,225 |
| Accrued CRO fees | 818 | 788 |
| Deferred grant funds | 551 | 301 |
| Accrued expense reimbursements | 33 | 33 |
| Accrued transaction costs | - | 1,354 |
| Other | 12 | 70 |
| | <u>\$ 2,730</u> | <u>\$ 3,960</u> |

7. Leases

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

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

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

In April 2020, we terminated an existing operating lease for office space. At the time of termination, we removed the remaining right-of-use asset of \$0.3 million, lease liability of \$0.3 million, and recognized a gain of \$51 thousand. 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 \$56 thousand, an increase in leasehold improvements of \$0.5 million, an increase in lease liability of \$0.4 million, and a gain on termination of \$51 thousand.

We have noncancelable operating lease arrangements primarily for office and lab space. We also have noncancelable finance leases for certain lab equipment. The maturity analysis of finance and operating lease liabilities as of March 31, 2021 are as follows:

| (in thousands) | Finance Leases | Operating Leases |
|---|-------------------|---------------------|
| 2022 | \$ 118 | 387 |
| 2023 | 135 | 433 |
| 2024 | 82 | 442 |
| 2025 | 21 | 454 |
| 2026 | - | 466 |
| Thereafter | - | 64 |
| Total undiscounted cash flows | <u>356</u> | <u>2,246</u> |
| Less amount representing interest/discounting | (7) | (321) |
| Present value of future lease payments | <u>349</u> | <u>1,925</u> |
| Less lease obligations, current portion | (139) | (202) |
| Lease obligations – long term portion | <u>\$ 210</u> | <u>\$ 1,723</u> |

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 March 31, 2021 and December 31, 2020 are summarized as follows:

| (in thousands) | March 31, 2021 | December 31, 2020 |
|-------------------------------|---------------------------|------------------------------|
| Lab equipment | \$ 920 | \$ 920 |
| Furniture and fixtures | 46 | 46 |
| Work in process | 228 | 228 |
| Total | 1,194 | 1,194 |
| Less accumulated depreciation | (629) | (593) |
| Net | <u>\$ 565</u> | <u>\$ 601</u> |

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

Operating Leases

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

Components of Lease Cost

The components of finance and operating lease costs for the three months ended March 31, 2021 and 2020 were as follows:

| (in thousands) | 2021 | 2020 |
|-------------------------------|---------------|---------------|
| Finance lease costs: | | |
| Amortization | \$ 37 | \$ 48 |
| Interest on lease liabilities | 8 | 11 |
| Operating lease costs | 70 | 81 |
| Short-term lease costs | 62 | 88 |
| Variable lease costs | 19 | 34 |
| Total lease costs | <u>\$ 196</u> | <u>\$ 262</u> |

Supplemental Cash Flow Information

| (in thousands) | 2021 | 2020 |
|--|-------------|-------------|
| Operating cash flows from operating leases | \$ (151) | \$ (203) |
| Operating cash flows from finance leases | \$ (8) | \$ (11) |
| Finance cash flows from finance leases | \$ (45) | \$ (53) |

8. Notes Payable

In February 2019, we entered into a loan agreement (the “**2019 MD Loan**”) with the Department of Housing and Community Development, a principal department of the State of Maryland (“**Maryland**”). Pursuant to the 2019 MD Loan, Maryland agreed to provide a \$0.5 million term loan. Amounts outstanding under the 2019 MD Loan bear simple interest at an annual rate of 8.00%. Under the 2019 MD Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include providing information about the Company and our operations; limitations on our ability to retire, repurchase, or redeem our common or preferred stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. There are no financial covenants associated with the Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on February 22, 2034. The 2019 MD Loan establishes “Phantom Shares,” based on 119,906 shares of our Common Stock (based on 863,110 Series C Preferred Shares prior to the Reverse Recapitalization), determined at issuance. The Loan Agreement states the repayment amount is to be the greater of the balance of principal and accrued interest or the Phantom 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 MD Loan is determined based on the closing price of CLNN shares listed on the Nasdaq. Expense of \$0.5 million and \$10 thousand was recognized during the three months ended March 31, 2021 and 2020, respectively. The fair value of \$1.5 million and \$1.1 million of principal and accrued interest is included in long-term notes payable as of March 31, 2021 and December 31, 2020, respectively.

In April 2019, we entered into a loan agreement (the “**2019 Cecil Loan**”) with Cecil County, Maryland (“**Cecil**”). Pursuant to the 2019 Cecil Loan, Cecil agreed to provide a \$0.1 million term loan. Amounts outstanding under the 2019 Cecil Loan bear simple interest at an annual rate of 8.00%. Under the 2019 Cecil Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include providing information about the Company and our operations; limitations on our ability to retire, repurchase, or redeem our common or preferred stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. There are no financial covenants associated with the Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on April 30, 2034. The 2019 Cecil Loan establishes “Phantom Shares,” based on 23,981 shares of our 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 now determined based on the closing price of CLNN shares listed on the Nasdaq. Expense of \$0.1 million and \$2 thousand was recognized during the three months ended March 31, 2021 and 2020, respectively. The fair value of \$0.3 million and \$0.2 million of principal and accrued interest is included in long-term notes payable as of March 31, 2021 and December 31, 2020, respectively.

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 three months ended March 31, 2021.

9. Preferred Stock Warrant Liability

Prior to the Reverse Recapitalization, we issued Series A Preferred Stock Warrants in 2013 in connection with certain note purchase agreements. The warrants expire 10 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 1,608,672 shares of the Series A Preferred Stock.

Prior to the Reverse Recapitalization, on April 8, 2013, we issued 10-year warrants to purchase units of our most senior equity equal to 0.50% of our fully diluted equity at the time of exercise in connection with certain note purchase agreements. As of December 31, 2019, these warrants were exercisable into 271,439 shares of our most senior equity, Series C Preferred Stock, at a fixed exercise price of \$1.97 per share. On August 11, 2020, in connection with our issuance of Series D Preferred Stock, these warrants became exercisable into 320,441 shares of our most senior equity, Series D Preferred Stock, at a fixed exercise price of \$1.97 per share.

Prior to the Reverse Recapitalization, we classified Preferred Stock warrants as a liability on the condensed consolidated balance sheets because the warrants are freestanding financial instruments that may have required us to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and is subsequently remeasured to fair value as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the Reverse Recapitalization (see Note 1), and pursuant to the Merger Agreement, all of the outstanding Clene Nanomedicine Preferred Stock was converted to the Clene Inc. Common Stock and the Clene Nanomedicine Preferred Stock warrants to purchase Clene Nanomedicine Preferred Stock were converted to warrants to purchase the Clene Inc. Common Stock (see Note 10). Upon conversion, we assessed the features of the warrants and determined that they qualify for classification as permanent equity upon the closing of the Reverse Recapitalization. Accordingly, we remeasured the warrants to fair value one final time upon the close of the Reverse Recapitalization, and recognized a loss of \$14.6 million for the year ended December 31, 2020, within other income, (expense), net on the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the Reverse Recapitalization, the warrant liability was reclassified to additional paid-in capital (see Notes 1 and 17).

As of March 31, 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 \$0.1 million during the three months ended March 31, 2020 in the condensed consolidated statements of operations and comprehensive loss.

10. Common Stock Warrants

As of March 31, 2021 and December 31, 2020, outstanding warrants to purchase shares of our Common Stock consisted of the following:

| <u>Date Exercisable</u> | <u>Number of Shares Issuable</u> | <u>Exercise Price</u> | <u>Exercisable for</u> | <u>Classification</u> | <u>Expiration</u> |
|-------------------------|----------------------------------|-----------------------|------------------------|-----------------------|-------------------|
| June 2021 | 1,119,750 | \$ 0.01 | Common Stock | Equity | December 2021 |
| December 2020 | 2,407,500 | \$ 11.50 | Common Stock | Equity | December 2025 |
| December 2020 | 110,000 | \$ 11.50 | Common Stock | Equity | December 2025 |
| December 2020 | 1,929,113 | \$ 1.97 | Common Stock | Equity | April 2023 |
| Total | 5,566,363 | | | | |

On December 28, 2020, the Company entered into a subscription agreement (the “**Subscription Agreement**”) with various investors for the private purchase of 2,239,500 shares of the Company’s Common Stock at a price of \$10.00 per share with net proceeds of \$22.2 million. Investors in the PIPE offering also received warrants (“**PIPE Warrants**”) to purchase a number of shares equal to one-half (1/2) of the number of PIPE Shares, totaling 1,119,750 shares of the Company’s Common Stock, at an exercise price of \$0.01 per share. Also, pursuant to the Subscription Agreement, the 1,119,750 PIPE Warrants are subject to a 180-day holding period. A holder of the PIPE Warrants may not exercise the PIPE Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company’s Common Stock outstanding immediately after giving effect to such exercise. As of March 31, 2021 and December 31, 2020, none of the warrants had been exercised.

In connection with the Reverse Recapitalization, all of Tottenham’s issued and outstanding warrants to purchase one-half (1/2) of one share of Tottenham’s ordinary shares totaling 2,407,500 shares issued in connection with Tottenham’s initial public offering, were automatically converted into 4,815,000 warrants to purchase 2,407,500 shares of the Company’s Common Stock. The warrants became exercisable upon the completion of the Reverse Recapitalization and will expire five years after the consummation of the Reverse Recapitalization (i.e., December 2025). 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 March 31, 2021 and December 31, 2020, none of the warrants had been exercised.

In connection with Tottenham's initial public offering in August 2018, Tottenham issued to Chardan options to purchase 220,000 units at \$10.00 per unit. Each of Tottenham's units consists of one and one-tenth shares of Tottenham's ordinary shares for \$10.00 per share and one warrant to purchase one-half of one Tottenham ordinary share at an exercise price of \$11.50 per share. In connection with the Reverse Recapitalization, the Chardan Unit Purchase Option was converted into one Company unit purchase option. The Chardan Unit Purchase Option Warrants are exercisable upon the completion of the Reverse Recapitalization and will expire in December 2025. As of March 31, 2021 and December 31, 2020, no Chardan Unit Purchase Options were exercised.

In connection with the Reverse Recapitalization, all of the 1,929,113 outstanding Series A and Series D Preferred Stock Warrants were converted automatically into 1,929,113 warrants to purchase shares of the Company Common Stock at \$1.97 per share (See Note 9). As of March 31, 2021 and December 31, 2020, none of the warrants had been exercised.

11. 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 redemption features that met the requirements for separate accounting and were accounted for as a single 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 \$8 thousand, including amortization of debt discount of \$20 thousand during the three months ended March 31, 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 1), and pursuant to the Merger Agreement, all outstanding Clene Nanomedicine Series D Preferred Stock was converted to Clene Inc. Common Stock.

We accounted for the conversion of the 2020 Convertible Notes as a debt extinguishment and recognized a loss on extinguishment of debt of \$0.5 million within other income (expense), net in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020. As of the date of conversion, the unamortized discount on the 2020 Convertible Notes was \$0.5 million. The loss on extinguishment was calculated as the difference between (i) the fair value of the 1,497,135 shares of Series D Preferred Stock issued to settle the 2020 Convertible Notes of \$6.9 million and (ii) the carrying value of the 2020 Convertible Notes, including the principal balance of the 2020 Convertible Notes of \$6.1 million and accrued but unpaid interest of \$76 thousand, net of the unamortized debt discount of \$5.7 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.

12. Derivative Instruments

Derivative instrument in connection with the 2020 Convertible Notes

One of the redemption features of the 2020 Convertible Notes met the requirements for separate accounting and was accounted for as a derivative instrument. The 2020 Derivative Instrument was recorded at fair value, which was \$0.7 million at issuance. In August 2020, in connection with our issuance and sale of Series D Preferred Stock, all of the outstanding principal and accrued interest under the 2020 Convertible Notes was automatically converted into shares of Series D Preferred Stock and the derivative liability was extinguished. Prior to the extinguishment of derivative liability, the 2020 Derivative Instrument was marked to fair value and we recorded the change in the 2020 Derivative Instrument of (\$29) thousand in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020 (see Note 11). For the three months ended March 31, 2020, we recorded the change in the 2020 Derivative Instrument of \$4 thousand in the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the Reverse Recapitalization (see Note 1), 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-out was subsequently remeasured to fair value at each reporting date as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

Upon the closing of the Reverse Recapitalization, we recognized the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out liabilities at their fair value of \$64.7 million and \$7.4 million, respectively, in the condensed consolidated balance sheets. As of December 31, 2020, the carrying values of the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out were \$52.1 million and \$5.9 million, respectively. As of March 31, 2021, the carrying values of the Clene Nanomedicine Contingent Earn-out and Initial Shareholders Contingent Earn-out were \$77.7 million and \$8.9 million, respectively. For the three months ended March 31, 2021, we recognized losses of \$25.6 million in change in fair value of the Clene Nanomedicine Contingent Earn-out and \$3.0 million in change in fair value of the Initial Shareholders Contingent Earn-out as components of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. To date, none of the milestones have been achieved.

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 have not recorded income tax benefits for the net operating losses incurred during the three months ended March 31, 2021 and 2020 nor 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 loss before income taxes for the three months ended March 31, 2021 and 2020 were as follows (in thousands):

| | Three Months Ended March 31, 2021 | Three Months Ended March 31, 2020 |
|---------------------------------------|--|--|
| United States | \$ (38,721) | \$ (3,386) |
| Foreign | (1,107) | (555) |
| Total loss before income taxes | \$ (39,828) | \$ (3,941) |

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 unit awards, 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 March 31, 2021, the Company's Board of Directors granted 1,634,804 restricted stocks units and stock options under the 2020 Stock Plan. As of March 31, 2021, 10,365,196 shares remained available for future grant.

As of December 31, 2020, the Company's Board of Directors granted 1,507,062 restricted stock units 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 (as described in Note 1), 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 for the three months ended March 31, 2021 and 2020 was approximately \$3.3 million and \$0.2 million, respectively. Stock-based compensation is recorded in research and development and general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss as follows:

| (In thousands) | Three months ended March 31, | |
|---------------------------------------|---|---------------|
| | 2021 | 2020 |
| General and administrative | \$ 1,870 | \$ 71 |
| Research and development | 1,395 | 100 |
| Total stock-based compensation | \$ 3,265 | \$ 171 |

As of March 31, 2021, we had approximately \$2.8 million of unrecognized stock-based compensation costs related to non-vested awards which is expected to be recognized over a weighted-average period of 2 years.

The following sets forth the outstanding Common Stock options and related activity for the three months ended March 31, 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 | 130,000 | 6.55 | 9.85 | - |
| Exercised | (48,211) | 1.04 | - | 384 |
| Forfeited | (8,579) | 4.32 | - | - |
| Outstanding - March 31, 2021 | 7,105,801 | \$ 1.07 | 5.17 | \$ 56,435 |
| Options vested and exercisable - March 31, 2021 | 5,966,739 | \$ 0.60 | 4.66 | \$ 50,173 |
| Options vested and exercisable - Stock options vested and expected to vest March 31, 2021 | 7,105,801 | \$ 1.07 | 5.17 | \$ 56,435 |

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 option pricing 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 three months ended March 31, 2021, we granted stock options for 130,000 shares under the 2020 Stock Plan. The assumptions used to calculate the value of the stock option awards granted for the three months ended March 31, 2021 are presented as follows:

| | Three months ended March 31, 2021 |
|---------------------------------|--|
| Expected stock price volatility | 84.80% |
| Risk-free interest rate | 0.59% |
| Expected dividend yield | 0% |
| Expected term of options | 6 years |

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2021 was \$6.55.

Restricted Stock Units

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

- 370,101 shares to various employees and non-employee directors, which vest on June 30, 2021, subject to the employee's continuous employment through such vesting date. 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 (as described in Note 1). The grant-date fair value of these awards was \$4.0 million. No shares were vested as of March 31, 2021 and December 31, 2020.
- 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 (as described in 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 March 31, 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 (as described in 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 March 31, 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 (as described in Note 3). The grant-date fair value of these awards was \$3.7 million based on a weighted average grant date fair value of \$10.82 per share. We did not recognize compensation expense because the occurrence of achieving this milestone was not probable. As of the March 31, 2021 and December 31, 2020 measurement dates, no shares were vested.

The following table summarizes the restricted common stock activity during the three months ended March 31, 2021:

| | Number of RSUs | Weighted- Average Grant Date Fair Value |
|--|-------------------|--|
| Outstanding and unvested balance as of December 31, 2020 | 1,507,062 | \$ 10.30 |
| Vested | - | - |
| Forfeited | (2,258) | 10.82 |
| Outstanding and unvested balance as of March 31, 2021 | 1,504,804 | \$ 7.59 |

The assumptions used to calculate the value of the restricted stock units 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 March 31, 2021 were as follows: (i) 85% of expected stock price volatility, (ii) risk-free interest rate of 0.6%, and (iii) expected term of 5 years. 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 5 years. The weighted average grant-date fair value of RSUs granted during the three months ended March 31, 2021 and as of December 31, 2020 was \$0 and \$10.3034, respectively.

The stock-based compensation expense associated with the RSUs was \$3.0 million and \$0 for the three months ended March 31, 2021 and 2020. As of March 31, 2021 and December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was \$8.4 million and \$15.5 million, which is expected to be recognized over a weighted average period of 3 months and 6 months, respectively. We did not issue any RSUs during the three months ended March 31, 2020.

16. Fair Value

The carrying amount of accounts payable approximates fair value because of the immediate, short-term maturity of these financial instruments.

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 March 31, 2021 and December 31, 2020 (in thousands):

| | Fair Value Measurements on a Recurring Basis | | | |
|--|--|---------|---------|----------|
| | March 31, 2021 | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| Notes payable | \$ 1,839 | \$ - | \$ - | \$ 1,839 |
| Clene Nanomedicine contingent earn-out | - | - | 77,663 | 77,663 |
| Initial Shareholders contingent earn-out | - | - | 8,867 | 8,867 |

| | Fair Value Measurements on a Recurring Basis | | | |
|--|--|---------|---------|----------|
| | December 31, 2020 | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| Notes payable | \$ 1,296 | \$ - | \$ - | \$ 1,296 |
| Clene Nanomedicine contingent earn-out | - | - | 52,054 | 52,054 |
| Initial Shareholders contingent earn-out | - | - | 5,906 | 5,906 |

Valuation of Notes Payable

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

As of March 31, 2021, the fair value of our notes payable is determined based on the closing price of \$12.78 per share as reported by the Nasdaq.

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

Valuation of Warrants to Purchase Preferred Stock

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

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

Upon the closing of the Reverse Recapitalization (see Note 1), 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 Contingent Earn-out

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 our Common Stock, respectively, upon us achieving certain milestones described in 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 our Common Stock. The Contingent Earn-outs were recorded at fair value on the closing of the Reverse Recapitalization on December 30, 2020 and remeasured at each reporting period. As of March 31, 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 March 31, 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:

| | March 31, 2021 | December 31, 2020 |
|---------------------------------|---------------------------|------------------------------|
| Expected stock price volatility | 87.50% | 85.00% |
| Risk-free interest rate | 0.40% | 0.40% |
| Expected term | 5 years | 5 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, and the Contingent Earn-outs measured at fair value for the three months ended March 31, 2021 and 2020 (in thousands):

| | Notes Payable | Clene Nanomedicine Contingent Earn-out | Initial Shareholders Contingent Earn-out |
|-----------------------------|--------------------------|---|---|
| Balance - December 31, 2020 | \$ 1,296 | \$ 52,054 | \$ 5,906 |
| Change in fair value | 543 | 25,609 | 2,961 |
| Balance - March 31, 2021 | <u>\$ 1,839</u> | <u>\$ 77,663</u> | <u>\$ 8,867</u> |

| | Notes Payable | Derivative Instrument | Preferred Stock Warrants |
|--|--------------------------|----------------------------------|---|
| Balance - December 31, 2019 | \$ 640 | \$ - | \$ 3,213 |
| Issuance of convertible promissory notes | - | 189 | - |
| Change in fair value | 12 | 4 | (112) |
| Balance - March 31, 2020 | <u>\$ 652</u> | <u>\$ 193</u> | <u>\$ 3,101</u> |

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 1). As of March 31, 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 December 31, 2020, our certificate of incorporation, as amended and restated, authorized us to issue 100,000,000 shares of Common Stock, par value \$0.0001 per share and 1,000,000 shares of Preferred Stock, par value \$0.0001 per share.

Our common 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 2,303,495 of the Tottenham ordinary shares held by the Initial Shareholders and public shareholders were converted into the same number our Common Stock (see Note 3).

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

On December 28, 2020 and prior to the closing of the Reverse Recapitalization, various PIPE investors purchased 2,239,500 shares of our Common Stock at a price of \$10.00 per share and 1,119,750 warrants to purchase, at an exercise price of \$0.01 per share, one share of our Common Stock for net proceeds of \$22.2 million (see Notes 1 and 3).

As of March 31, 2021 and December 31, 2020, our common shares issued and outstanding were 59,574,382 and 59,526,171, respectively. As of March 31, 2021 and December 31, 2020, there were no preferred shares issued and outstanding (see Note 17).

19. Net Loss Per Share Attributable to Common Shareholders

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

| | Three months ended March 31, | |
|---|------------------------------|------------|
| | 2021 | 2020 |
| Numerator: | | |
| Net loss attributable to common shareholders | \$ (39,756) | \$ (3,941) |
| Denominator: | | |
| Weighted average shares outstanding | 60,670,932 | 17,357,505 |
| Net loss per share attributable to common shareholders, basic and diluted | \$ (0.66) | \$ (0.23) |

Included within weighted average common shares outstanding as of March 31, 2021 are 1,119,750 common shares issuable upon the exercise of the PIPE warrants as the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common shareholders.

We have not considered the effect of the Chardan Unit Purchase Option that would convert to 242,000 shares of our Common Stock and warrants to purchase 110,000 shares of our Commons Stock, in the calculation of diluted loss per share, since the conversion of the Chardan Unit Purchase Option and the exercise of the Chardan Unit Purchase Option Warrants into our Commons Stock would be anti-dilutive (see Notes 1 and 10).

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

| | Three months ended March 31, | |
|---|---------------------------------|------------|
| | 2021 | 2020 |
| Series C redeemable convertible preferred stock | - | 7,264,519 |
| Series B redeemable convertible preferred stock | - | 4,168,815 |
| Series A redeemable convertible preferred stock | - | 16,066,503 |
| Series C redeemable convertible preferred stock warrants | - | 271,439 |
| Series A redeemable convertible preferred stock warrants | - | 1,608,672 |
| Common stock warrants (see Note 10) | 4,336,613 | - |
| Options to purchase common stock | 7,105,801 | 7,240,181 |
| Chardan Unit Purchase Option to purchase common stock (see Note 1) | 242,000 | - |
| Chardan Unit Purchase Option Warrants (see Notes 1 and 10) | 110,000 | - |
| Clene Nanomedicine contingent earn-out shares (see Note 3 and 12) | 8,346,185 | - |
| Initial Shareholders contingent earn-out shares (see Note 3 and 12) | 750,000 | - |
| Total | 20,890,599 | 36,620,130 |

20. Related Party Transactions

Supply Agreement

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 will be for a term of 5 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 5-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 months ended March 31, 2021, we sold \$0.2 million of product under this agreement and received \$0.1 million in advance to be applied against future sales of product under this agreement. We did not sell any products outside of this agreement. We recorded this advanced amount as deferred revenue as of March 31, 2021 within accrued liabilities, and we expect to fulfil the performance obligations to release the deferred revenue in the first half of 2021 as the investor purchases product. For the three months ended March 31, 2020, the investor has made commercial sales of their products under the agreement which we recognized as royalty revenues of \$14 thousand. For the three months ended March 31, 2020, we did not sell any product under this agreement, and there were no balances outstanding due to or from the investor.

21. Geographic and Segment Information

Geographic Information

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

| | As of March 31, 2021 | As of December 31, 2020 |
|-----------------------------------|----------------------------|-------------------------------|
| United States | \$ 4,018 | \$ 3,997 |
| Australia | 164 | 228 |
| Total property and equipment, net | <u>\$ 4,182</u> | <u>\$ 4,225</u> |

Segment Information

We have two operating segments: (i) development and commercialization of proprietary nanotechnology drug suspensions (“**Drugs**”), and (ii) development and commercialization of proprietary dietary supplements (“**Supplements**”).

The operating results of the Drugs and Supplements segments for the three months ended March 31, 2021 and 2020 were as follows (in thousands):

| | For the Three Months ended March 31, 2021 | | |
|---------------------------------|---|-------------|-------------|
| | Drugs | Supplements | Total |
| Revenue from external customers | \$ - | \$ 213 | \$ 213 |
| Loss from operations | \$ (11,665) | \$ (30) | \$ (11,695) |

| | For the three months ended March 31, 2020 | | |
|---------------------------------|---|-------------|------------|
| | Drugs | Supplements | Total |
| Revenue from external customers | \$ - | \$ 70 | \$ 70 |
| (Loss) Income from operations | \$ (4,014) | \$ 12 | \$ (4,002) |

Our long-lived assets, which were composed of property and equipment, net by segment was as follows (in thousands):

| | As of March 31, 2021 | As of December 31, 2020 |
|-----------------------------------|----------------------------|-------------------------------|
| Drugs | \$ 3,958 | \$ 3,990 |
| Supplements | 224 | 235 |
| Total property and equipment, net | <u>\$ 4,182</u> | <u>\$ 4,225</u> |

22. Subsequent Events

On April 19, 2021, the registration statement on Form S-1 referred to in Note 1 was declared effective by the SEC (file number 333-253173).

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations and other parts of this Quarterly Report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the “Securities Act”), as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The forward-looking statements include, but are not limited to, our expectations, hopes, beliefs, intentions, strategies, estimates and assumptions concerning events and financial trends that may affect our future results of operations or financial condition. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on information available as of the date of this Quarterly Report and our management’s current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We disclaim any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as specifically required under applicable securities laws.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes appearing in Part I, Item I of this Quarterly Report on Form 10-Q and with our Annual Report on Form 10-K for the year ended December 31, 2020 (the “2020 Annual Report”) which was filed with the SEC on March 29, 2021, pursuant to Rule 424(b) (4) under the Securities Act, as amended.

Business Overview

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

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

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

On December 30, 2020, Chelsea Worldwide, Inc., our predecessor company, consummated the previously announced business combination (referred to as the **“Reverse Recapitalization”**) pursuant to a merger agreement, dated as of September 1, 2020 (the **“Merger Agreement”**), by and among Clene Nanomedicine, Inc. (**“Clene Nanomedicine”**), Tottenham Acquisition I Limited (**“Tottenham”** or **“TOTA”**), the public entity prior to the Reverse Recapitalization, Chelsea Worldwide Inc., a Delaware corporation and wholly-owned subsidiary of Tottenham (**“PubCo”**), Creative Worldwide Inc., a Delaware corporation and wholly-owned subsidiary of PubCo (**“Merger Sub”**), and Fortis Advisors LLC, a Delaware limited liability company as the representative of our shareholders (**“Shareholders’ Representative”**). Prior to the Reincorporation Merger discussed below, Tottenham was incorporated in the British Virgin Islands as a blank check company for the purpose of entering into a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combination with one or more businesses or entities.

The Reverse Recapitalization was effected in two steps: (i) Tottenham was reincorporated to the state of Delaware by merging with and into PubCo (the **“Reincorporation Merger”**); (ii) promptly following the Reincorporation Merger, Merger Sub was merged with and into Clene Nanomedicine, resulting in Clene Nanomedicine being a wholly-owned subsidiary of PubCo (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 (**“Common Stock”**) on the Nasdaq Stock Exchange (the **“Nasdaq”**) under the symbol **“CLNN.”** As a result of the Reverse Recapitalization, Clene Nanomedicine became a wholly-owned direct subsidiary of Clene Inc. For periods prior to the closing of the Reverse Recapitalization on December 30, 2020, the disclosure in Management’s Discussion and Analysis of Financial Condition and Results of Operations has been updated to give effect to the Reverse Recapitalization.

We filed a registration statement on Form S-1 to register 4,541,481 shares of Common Stock underlying outstanding warrants that we had previously issued, which the SEC declared to be effective on April 19, 2021 (file number 333-253173). We will receive aggregate gross proceeds of \$30.7 million if all of these warrants are exercised. In conjunction with the preparation of the registration statement on Form S-1, we incurred offering costs of \$27 thousand, which were recognized as an expense within general and administrative expenses in the condensed consolidated statement of operations for the three months ended March 31, 2021.

We currently have no drugs approved by the US Food and Drug Administration (**“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 \$11.7 million and \$4.0 million for the three months ended March 31, 2021 and 2020, respectively. Substantially all of our losses from operations resulted from research and development expenses and administrative expenses. As of March 31, 2021 and December 31, 2020, we had an accumulated deficit of \$193.3 million and \$153.6 million, respectively.

We expect to continue investing in product development, sales and marketing and customer support for our products and expect to incur additional losses in the future to fund our operations and conduct product research and development. We also recognize the need to raise additional capital to fully implement our business plan. The long-term continuation of our business plan is dependent upon the generation of sufficient revenues from our products to offset expenses and capital expenditures. In the event that we do not generate sufficient revenues and are unable to obtain funding, we will be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion, commercialization efforts or capital expenditures, which could adversely affect our business prospects, ability to meet long-term liquidity needs or we may be unable to continue operations.

Impact of the COVID-19 Coronavirus Pandemic

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

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

Reverse Recapitalization with Tottenham and Clene Nanomedicine

On December 30, 2020, we completed the previously announced Reverse Recapitalization (see “*Business Overview*” above).

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

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

Immediately after giving effect to the Reverse Recapitalization and the PIPE offering discussed in below, 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.

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 Offering

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

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 will be subsequently remeasured to fair value at each reporting date. The change in fair value of the Contingent Earn-outs has been recorded in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 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 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 volume-weighted average price of the shares of our Common Stock within five years after the closing of the Reverse Recapitalization or the change of control price equaling or exceeding a certain price if a change of control transaction occurs within the five years following the closing of the Reverse Recapitalization, and (iii) Milestone 3 that is based on completing by December 30, 2021 a randomized placebo-controlled study for treatment of COVID-19 coronavirus.

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

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

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

Research and Development Expenses

The discovery and development of novel drug candidates require a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been advancing and expanding, with two clinical-stage drug candidates currently being investigated.

We anticipate that our research and development expenses will increase significantly due to the increase in clinical trial expenses incurred to develop our drug candidates, expenses incurred for payments to CROs, principal investigators and clinical trial sites, costs of materials to support our clinical trials and preclinical studies, costs associated with preclinical activities, share awards granted to our research and development personnel and salaries for our expanding research and development personnel headcount. 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, and the consummation of the Reverse Recapitalization.

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 external lenders;
- gross cash proceeds of \$31.7 million through the Reverse Recapitalization and the PIPE offering;
- gross cash proceeds of \$0.6 million from a Program Paycheck Protection loan obtained through the U.S. Small Business Administration. This loan was forgiven in January 2021; and
- gross cash proceeds of \$0.5 million from a grant from the Michael J. Fox Foundation obtained in January 2021 for our preclinical research funding.

We have also been awarded grants from various other organizations, including the U.S. Congressionally Directed Medical Research Program administered by the Department of Defense, the National Multiple Sclerosis Society, and FightMND, a not-for-profit registered charity in Australia, who together have issued us grants totaling approximately \$2.9 million. We also receive indirect financial support for one of the clinical studies in which we participate, the Healey ALS Platform Trial, administered by the Massachusetts General Hospital, which is conducting a study of our CNM-Au8 drug candidate along with other drugs in a platform trial, at significantly lower costs to us than we would otherwise incur if we were to conduct a comparably designed study on our own at reasonable market rates.

The net cash used in our operating activities was \$9.2 million and \$3.3 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had cash of \$48.0 million. We expect that the cash on hand as of March 31, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date the condensed consolidated financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we may exhaust our available capital resources sooner than we anticipate. See “— *Liquidity and Capital Resources.*” We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug products and continue research and development of our preclinical drug products and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug products. As we continue to grow and expand, we will incur more expenses relating to regulatory compliance and sales and marketing personnel as we prepare to commence commercialization once we obtain regulatory approval of our drug products.

General and Administrative Expenses

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

Grants and Government Tax Incentives

We received grants issued by non-government entities related to income which have future related costs expected to be incurred and require us to comply with conditions attached to the grants. These non-government grants related to income are recognized in profit or loss as an offset to research and development expenses when funding has been received and related costs have been incurred. We received tax incentives from the Australian government in the form of cash subsidies for research and development activities related to clinical trial activities conducted by our Australian subsidiary, which are recognized as other income upon compliance with certain conditions. We did not recognize grant funding against research and development expenses for the three months ended March 31, 2021. We recognized \$0.2 million of grant funding against research and development expenses for the three months ended March 31, 2020. We recognized \$0.3 million of other income for the three months ended March 31, 2021 that we classified as Australia research and development credit. We did not recognize other income for the three months ended March 31, 2020.

Commercialization of Our Drug Candidates

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

Components of Results of Operations

Comparison of the three months ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

| | Three Months ended March 31, | |
|--|---------------------------------|-------------------|
| | 2021 | 2020 |
| | <i>(in thousands)</i> | |
| Product revenue | \$ 199 | \$ 70 |
| Royalty revenue | 14 | - |
| Total revenue | <u>213</u> | <u>70</u> |
| Operating expenses: | | |
| Cost of revenue | 243 | 58 |
| Research and development | 6,275 | 3,202 |
| General and administrative | 5,390 | 812 |
| Total operating expenses | <u>11,908</u> | <u>4,072</u> |
| Loss from operations | (11,695) | (4,002) |
| Other income (expenses): | | |
| Interest expense | (551) | (51) |
| Gain on extinguishment of debt | 647 | - |
| Change in fair value of preferred stock warrant liability | - | 112 |
| Change in fair value of derivative liability | - | 4 |
| Change in fair value of Clene Nanomedicine contingent earn-out | (25,610) | - |
| Change in fair value of Initial Shareholders contingent earn-out | (2,961) | - |
| Australia research and development credit | 339 | - |
| Other income, net | 3 | (4) |
| Total other income (expense), net | <u>(28,133)</u> | <u>61</u> |
| Net loss before income taxes | (39,828) | (3,941) |
| Income tax benefit | 72 | - |
| Net loss | <u>(39,756)</u> | <u>(3,941)</u> |
| Other comprehensive income (loss): | | |
| Foreign currency translation adjustments | 24 | 6 |
| Total other comprehensive income (loss) | <u>24</u> | <u>6</u> |
| Comprehensive loss | <u>\$ (39,732)</u> | <u>\$ (3,935)</u> |

Revenue

We generated revenue of \$0.2 million and \$70 thousand for the three months ended March 31, 2021 and 2020, respectively, which we separate as product revenue and royalty revenue. Product revenue of \$0.2 million and \$70 thousand 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 also generated minimal product revenue from sales of rMetx™ ZnAg Immune Boost during those periods. In addition, \$14 thousand of our revenue during the three months ended March 31, 2021 was paid to us by 4Life Research, LLC under an exclusive and royalty-bearing license agreement relating to sales of KHC46. We did not generate royalty revenue during the three months ended March 31, 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 on Form 10-Q.

Operating Expenses

Cost of Sales

We incurred cost of sales of \$0.2 million and \$58 thousand for the three months ended March 31, 2021 and 2020, respectively, relating to production and distribution costs for the sales of our KHC46 and low dose zinc-silver solution dietary supplement products through supply agreements we have entered into with a related party.

Research and Development Expenses

Research and development expenses were \$6.3 million and \$3.2 million, representing 52.7%, and 78.6% of our total operating expenses for the three months ended March 31, 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. This increase of \$3.1 million, or 96.0%, was 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 March 31, 2021, Research and Development expenses included \$1.3 million of share-based compensation expense related to RSUs.

Historically, substantially all of our research and development expenses relate to CNM-Au8, our lead asset. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to per patient clinical trial site fees for larger studies, the costs of opening and monitoring clinical sites, CRO activity, and manufacturing expenses. We expect that our research and development expenses will increase in connection with our clinical development activities in the near term and in the future.

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

Our clinical trial accrual process seeks to account for expenses resulting from obligations under contracts with CROs, consultants, and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We reflect the appropriate trial expenses in the condensed consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments will be recorded as a prepaid asset, which will be expensed over the period of time the contracted services are performed.

General and Administrative Expenses

General and administrative expenses consist of employee salary and benefits, share-based compensation expenses, professional fees for legal, consulting and audit services and business development activities, facility, 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 \$5.4 million and \$0.8 million for the three months ended March 31, 2021 and 2020, respectively. This increase of \$4.6 million, or 563.8% was primarily due to (i) increased professional expenses, public company expenses, legal fees, accounting fees, tax fees, and director and officer insurance policies as a result of becoming a public company on December 30, 2020 to support our efforts to comply with SEC rules and regulations, and (ii) \$1.9 million of share-based compensation expense related to RSUs.

Other Income (Expenses)

Other income (expenses) consists of interest expenses, interest income, changes in fair value of preferred stock warrant liability, changes in fair value of derivative liability, change in fair value of contingent earn-out, a research and development credit received from the Australian government, foreign exchange gain, gain on disposal of assets, and loss on extinguishment of notes payable. Other income (expenses), net for the three months ended March 31, 2021 and 2020 included the following:

(i) recognized interest expense of \$0.6 million and \$51 thousand, respectively, due to an increase in the fair value of our notes payable. As of March 31, 2021, the fair value of our notes payable is determined based on the closing price of CLNN shares listed on the Nasdaq of \$12.78 per share.

(ii) recognized gain on extinguishment of notes payable of \$0.6 million, due to the forgiveness of the PPP Loan by the U.S. Small Business Administration. There was no gain on extinguishment of notes payable for the three months ended March 31, 2020.

(iii) recognized expense of \$112 thousand relating to the changes in fair value of preferred stock warrant liability for the three months ended March 31, 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 the change in fair value of our Clene Nanomedicine contingent earn-out liability of \$25.6 million for the three months ended March 31, 2021. The change in fair value was primarily a result of the increase of the closing price of CLNN shares listed on the Nasdaq for \$12.78 per share on March 31, 2021 from \$9.01 per share on December 31, 2020 when we remeasured the Clene Nanomedicine contingent earn-out liability at December 31, 2020.

(v) recognized the change in fair value of our Initial Shareholders contingent earn-out liability of \$3.0 million for the three months ended March 31, 2021. The change in fair value was primarily a result of the increase of the closing price of CLNN shares listed on the Nasdaq for \$12.78 per share on March 31, 2021 from \$9.01 per share on December 31, 2020 when we remeasured the Initial Shareholders contingent earn-out liability at December 31, 2020.

(vi) recognized income of \$0.3 million relating to a research and development credit received from the Australian government for the three months ended March 31, 2021. We did not recognize income relating to research and development credit received from the Australian government for the three months ended March 31, 2020. 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 increase in research and development credit is the result of increased research and development activities during the three months ended March 31, 2021.

Comprehensive Loss

As a result of the foregoing, we incurred a comprehensive loss of \$39.7 million and \$3.9 million for the three months ended March 31, 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 months ended March 31, 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 three months ended March 31, 2021 and 2020. We recorded a full valuation allowance against our net deferred tax assets due to the uncertainty as to whether such assets will be realized resulting from our three-year cumulative loss position and the uncertainty surrounding our ability to generate pre-tax income in the foreseeable future.

Australia

Our wholly-owned subsidiary, Clene Australia Pty Ltd, was established in Australia on March 5, 2018 and is subject to corporate income tax at a rate of 27.5%. Clene Australia total income tax benefit was \$72 thousand for the three months ended March 31, 2021. During the three months ended March 31, 2020, Clene Australia had no taxable income and therefore, no provision for income taxes was required. We recorded \$0.3 million as other income during the three months ended March 31, 2021 for a refund of research and development credits pertaining to Clene Australia for the 2021 tax year. We did not record any other income during the three months ended March 31, 2020 for a refund of research and development credits pertaining to Clene Australia for the 2020 tax year.

Netherlands

Our wholly-owned subsidiary, Clene Netherlands B.V., was established in the Netherlands on April 21, 2021 and will be subject to corporate income tax at a rate of 15% up to €245,000 of taxable income and 25% for taxable income in excess of €245,000. As Clene Netherlands was established subsequent to the quarter ended March 31, 2021, it had no taxable income and therefore, no provision for income taxes was required.

JOBS Act

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

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

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

Smaller Reporting Company Status

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

Liquidity and Capital Resources

Since inception, we have incurred annual net losses from our operations. Substantially all of our losses have resulted from the funding of our research and development programs and general and administrative expenses associated with our operations. We incurred net losses of \$39.8 million and \$3.9 million for the three months ended March 31, 2021 and 2020, respectively. Our loss from operations was \$11.7 million and \$4.0 million for the three months ended March 31, 2021 and 2020, respectively. We have financed our operations principally through proceeds from the sale of preferred stock, the sale of preferred stock warrants and the sale of convertible notes that have converted into shares of preferred stock, and through the funds we raised from the consummation of the Reverse Recapitalization and the PIPE offering. During the three months ended March 31, 2021, we did not raise any significant funds. During the three months ended March 31, 2020, we raised an aggregate of \$1.6 million, consisting of net proceeds from issuance of notes payable. We filed a registration statement on Form S-1 to register 4,541,481 shares of Common Stock underlying outstanding warrants that we had previously issued, which the SEC declared to be effective on April 19, 2021 (file number 333-253173). We will receive aggregate gross proceeds of \$30.7 million if all of these warrants are exercised.

The net cash used in our operating activities was \$9.2 million and \$3.3 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had cash of \$48.0 million. We expect that the cash on hand as of March 31, 2021 will be sufficient to fund our operations for a period extending beyond twelve months from the date the condensed consolidated financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we may exhaust our available capital resources sooner than we anticipate. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug products and continue research and development of our preclinical drug products and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug products. As we continue to grow and expand, we will incur more expenses relating to regulatory compliance and sales and marketing personnel as we prepare to commence commercialization once we obtain regulatory approval of our drug products.

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

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

| | Three months ended | |
|---|---------------------------|----------------|
| | March 31, | |
| | 2021 | 2020 |
| | <i>(in thousands)</i> | |
| Net cash used in operating activities | \$ (9,161) | \$ (3,251) |
| Net cash used in investing activities | (203) | (23) |
| Net cash provided by (used in) financing activities | (1,896) | 1,547 |
| Net effect of foreign exchange rate changes | 26 | 55 |
| Net decrease in cash | <u>(11,234)</u> | <u>(1,672)</u> |

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 \$9.2 million of cash for the three months ended March 31, 2021, which resulted from a net loss of \$39.8 million, adjusted for (i) non-cash items of \$32.0 million, which primarily consisted of depreciation expense of \$0.2 million, stock-based compensation expenses of \$3.3 million, changes in fair value of the Clene Nanomedicine contingent earn-out of \$25.6 million, changes in fair value of the Initial Shareholders contingent earn-out of \$3.0 million, gain on extinguishment of debt of \$0.6 million and increase in interest accrued on notes payable and accretion of debt discount of \$0.5 million, and (ii) a net decrease in operating assets and liabilities of \$1. million. The net decrease in operating assets and liabilities was primarily attributable to an increase in inventory of \$0.2 million, an increase in accounts receivable of \$0.1 million, an increase in prepaid expenses and other current assets of \$1.3 million due to the increase in Australia research and development credit receivable and prepayments to CROs and other vendors, \$0.2 million increase in accounts payable, \$0.1 million decrease in operating lease obligations, and \$0.1 million increase in accrued liabilities due to the timing of vendor invoicing and payments.

Net cash used in operating activities was \$3.3 million of cash for the three months ended March 31, 2020, which resulted from a net loss of \$3.9 million, adjusted for (i) non-cash items of \$0.3 million, which primarily consisted of depreciation expense of \$0.2 million, stock-based compensation expenses of \$0.2 million, and changes in the fair value of preferred stock warrant liability of \$0.1 million, and (ii) a net decrease in operating assets and liabilities of \$0.4 million. The net decrease in operating assets and liabilities was primarily attributable to an increase in prepaid expenses and other current assets of \$0.1 million due to the increase in other vendors, \$0.6 million increase in accounts payable, and \$0.1 million decrease in accrued liabilities due to the timing of vendor invoicing and payments.

Investing Activities

Net cash used in investing activities was \$0.2 million and \$23 thousand for the three months ended March 31, 2021 and 2020, respectively, which in each instance was related to purchases of property and equipment.

Financing Activities

Net cash used in financing activities was \$1.9 million for the three months ended March 31, 2021, which primarily resulted from payments of deferred offering costs of \$1.9 million and payments on our finance lease obligations of \$45 thousand, partially offset by proceeds from issuance of common stock upon exercise of common stock options of \$50 thousand.

Net cash provided by financing activities was \$1.5 million for the three months ended March 31, 2020, which primarily resulted from proceeds from the issuance of notes payable of \$1.6 million partially offset by payments on our finance lease obligations of \$0.1 million.

Debt Obligations

In February 2019, we entered into a loan agreement (the “**2019 MD Loan**”) with the Department of Housing and Community Development, a principal department of the State of Maryland (“**Maryland**”). Pursuant to the 2019 MD Loan, Maryland agreed to provide a \$0.5 million term loan. Amounts outstanding under the 2019 MD Loan bear simple interest at an annual rate of 8.00%. Under the 2019 MD Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include providing information about the Company and our operations; limitations on our ability to retire, repurchase, or redeem our common or preferred stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. There are no financial covenants associated with the Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on February 22, 2034. The 2019 MD Loan establishes “Phantom Shares,” based on 119,906 shares of our Common Stock (based on 863,110 Series C Preferred Shares prior to the Reverse Recapitalization), determined at issuance. The Loan Agreement states the repayment amount is to be the greater of the balance of principal and accrued interest or the Phantom Shares value. We determined that the note should be accounted for at fair value. We record the fair value of the debt at the end of each reporting period. In order to value the note, we consider the amount of the simple interest expense that would be due and the value of Phantom Shares. Upon the closing of the Reverse Recapitalization and as of December 31, 2020, the fair value of the 2019 MD Loan is determined based on the closing price of CLNN shares listed on the Nasdaq. Expense of \$0.5 million and \$10 thousand was recognized during the three months ended March 31, 2021 and 2020, respectively. The fair value of \$1.5 million and \$1.1 million of principal and accrued interest is included in long-term notes payable as of March 31, 2021 and December 31, 2020, respectively.

In April 2019, we entered into a loan agreement (the “**2019 Cecil Loan**”) with Cecil County, Maryland (“**Cecil**”). Pursuant to the 2019 Cecil Loan, Cecil agreed to provide a \$0.1 million term loan. Amounts outstanding under the 2019 Cecil Loan bear simple interest at an annual rate of 8.00%. Under the 2019 Cecil Loan, we agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include providing information about the Company and our operations; limitations on our ability to retire, repurchase, or redeem our common or preferred stock, options, and warrants other than per the terms of the securities; and limitations on our ability to pay dividends of cash or property. There are no financial covenants associated with the Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to the Company. We are not in violation of any affirmative or negative covenants. Repayment of the full balance outstanding is due on April 30, 2034. The 2019 Cecil Loan establishes “Phantom Shares,” based on 23,981 shares of our 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 the Nasdaq. Expense of \$0.1 million and \$2 thousand was recognized during the three months ended March 31, 2021 and 2020, respectively. The fair value of \$0.3 million and \$0.2 million of principal and accrued interest is included in long-term notes payable as of March 31, 2020 and December 31, 2020, respectively.

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 redemption feature at the next equity financing met the requirements of an embedded derivative to be bifurcated and recorded at fair value. We bifurcated the embedded feature at issuance and recorded a derivative liability of \$0.7 million at inception in conjunction with a discount on debt to be amortized over the life of the note. We recognized interest expense of \$8 thousand, including amortization of debt discount of \$20 thousand during the three months ended March 31, 2020, in connection with the 2020 Convertible Notes. We also identified two other embedded features in these convertible promissory notes that were not bifurcated, which were the conversion into Series C preferred shares upon maturity and the redemption upon a liquidation event. On August 11, 2020, in connection with our issuance and sale of Series D Preferred Stock prior to the Reverse Recapitalization, 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. 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 statement of operations and comprehensive loss for the year ended December 31, 2020. As of the date of conversion, the unamortized discount on the 2020 Convertible Notes was \$0.5 million. The loss on extinguishment was calculated as the difference between (i) the fair value of the 1,497,135 shares of Series D Preferred Stock issued to settle the 2020 Convertible Notes of \$6.9 million and (ii) the carrying value of the 2020 Convertible Notes, including the principal balance of the 2020 Convertible Notes of \$6.1 million and accrued but unpaid interest of \$76 thousand, net of the unamortized debt discount of \$5.7 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.

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 three months ended March 31, 2021.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and other commitments as of March 31, 2021, as compared to those disclosed in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our 2020 Annual Report which was filed with the SEC on March 29, 2021.

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, subject to payment of our remaining obligations under binding purchase orders and, in certain cases, nominal early termination fees. These commitments are not deemed significant.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Our most critical accounting policies are described under the heading “*Management’s Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies*” in Part II, Item 7 of our 2020 Annual Report which was filed with the SEC on March 29, 2021. There were no material changes to our critical accounting policies through March 31, 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, “Notes to Condensed Consolidated Financial Statements” of this Quarterly Report on Form 10-Q 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 March 31, 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 March 31, 2021, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting described below. Notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and Chief Financial Officer, believes the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Material Weaknesses in Internal Control over Financial Reporting

In connection with the audit of our financial statements as of and for the years ended December 31, 2020 and 2019, our management identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified relate to the fact that we did not design or maintain an effective control environment commensurate with our financial reporting requirements, including (a) lack of a sufficient number of trained professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately, and (b) lack of structures, reporting lines and appropriate authorities and responsibilities to achieve financial reporting objectives. This deficiency in our control environment contributed to the following additional deficiencies (each of which individually represents a material weakness) in our internal control over financial reporting:

- we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries;
- we did not design and maintain effective controls over segregation of duties related to manual journal entries. Specifically, certain personnel have the ability to both prepare and post manual journal entries without an independent review by someone without the ability to prepare and post manual journal entries;
- we did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions. Specifically, we did not design and maintain controls to analyze, account for and disclose warrants to purchase preferred stock and convertible promissory notes with embedded derivatives, including ensuring complete and accurate data was used in the valuations; and
- we did not design and maintain effective controls over certain information technology (“IT”) general controls for IT systems that are relevant to the preparation of the financial statements. Specifically, we did not design and maintain: (a) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate personnel of Clene, (b) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (c) computer operations controls to ensure that data backups are authorized and monitored, and (d) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

The control deficiencies described above resulted in the misstatement of our redeemable convertible preferred stock warrant liability, accrued liabilities, general and administrative expenses, Australian research and development credit, and amounts and classification within our statement of cash flows and related financial disclosures as of and for the year ended December 31, 2019 and in the misstatement of our prepaid expenses and other current assets, accrued liabilities, earn-out liabilities, redeemable convertible preferred stock warrant liability, general and administrative expenses, amounts and classification within our statement of equity, and amounts and classification within our statement of cash flows and related financial disclosures as of and for the year ended December 31, 2020. Additionally, each of the control deficiencies described above could result in a misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that each of the control deficiencies described above constitute material weaknesses.

Material Weakness Remediation

Management is actively engaged and committed to taking the steps necessary to remediate the control deficiencies that constituted the above material weakness. During 2020, we made the following enhancements to our control environment:

- we added finance personnel to the organization to strengthen our internal accounting team, to provide oversight, structure and reporting lines, and to provide additional review over our disclosures to include a Chief Financial Officer and a Manager of SEC Reporting;
- we engaged outside consultants to assist in the design, implementation, and documentation of internal controls that address the relevant risks, are properly designed, and provide for appropriate evidence of performance of the internal control; and
- we engaged outside consultants to assist us in the evaluation of a new Enterprise Resource Planning (“ERP”) system in order to mitigate the internal control gaps and limitations that cannot be addressed by the current ERP around segregation of duties, and to enhance the information technology general controls environment.

Our remediation activities are continuing during 2021. In addition to the above actions, we expect to engage in additional activities, including, but not limited to:

- adding more technical accounting resources to enhance our control environment;
- until we have sufficient technical accounting resources, engaging external consultants to provide support and to assist us in our evaluation of more complex applications of GAAP, and to assist us with documenting and assessing our accounting policies and procedures;
- implementing a new ERP to enhance the accuracy of our financial records, enable the enforcement of systematic segregation of duties, and to 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 March 31, 2021, we began implementing a new ERP to enhance the accuracy of our financial records, enable the enforcement of systematic segregation of duties, and to improve our information technology general controls environment.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We may be subject to legal proceedings, investigations and claims incidental to the conduct of our business from time to time. We are not currently a party to any material litigation or other legal proceedings brought against us. We are also not aware of any legal proceeding, investigation or claim, or other legal exposure that has a more than remote possibility of having a material adverse effect on our business, financial condition or results of operations.

ITEM 1A. RISK FACTORS

Our business, financial condition and results of operations can be affected by a number of factors, whether currently known or unknown, including but not limited to those described in Part I, Item 1A, “Risk Factors” of our 2020 Annual Report on Form 10-K (“**2020 Annual Report**”) which was filed with the SEC on March 29, 2021. There have been no material changes to our risk factors since the 2020 Annual Report. Any one or more of these factors could, directly or indirectly, cause our actual financial condition and results of operations to vary materially from past, or from anticipated future, financial condition and results of operations. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price.

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

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds

We entered into subscription agreements with various investors for the private placement of Common Stock (the “**Private Placement**”), all of which closed shortly before the closing of the Reverse Recapitalization. Under the Private Placement, 2,239,500 shares of Common Stock (the “**PIPE Shares**”) were sold, resulting in net proceeds of \$22.2 million. Pursuant to the subscription agreements, investors in the Private Placement also received warrants to purchase a number of shares equal to one-half (1/2) of the number of PIPE Shares, totaling 1,119,750 shares of PubCo Common Stock, at an exercise price of \$0.01 per share for each of the PIPE Shares (the “**PIPE Warrants**”), subject to a 180-day holding period. We filed a registration statement on Form S-1 to register the PIPE Shares and the Common Stock underlying the PIPE Warrants, which the SEC declared to be effective on April 19, 2021 (file number 333-253173).

We have been using and will continue to use these proceeds primarily (1) to fund our VISIONARY-MS, REPAIR-MS, REPAIR-PD, and RESCUE-ALS studies, and for our participation in the Healey-ALS Platform Trial, and our other clinical research and development activities, and (2) for general and administrative purposes.

(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 |
|----------------|---|
| 2.1 | Merger Agreement, dated as of September 1, 2020 (incorporated by reference to Annex A-1 to the Proxy Statement/Consent Solicitation Statement/Prospectus on Form S-4 filed by the Registrant on September 10, 2020). |
| 3.1 | 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 January 5, 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). |
| 4.1 | Specimen TOTA Warrant Certificate (incorporated by reference to Exhibit 4.4 to the Tottenham Registration Statement on Form S-1 filed with the Securities & Exchange Commission on July 5, 2018). |
| 4.2 | Warrant Agreement, dated August 1, 2018, by and between Continental Stock Transfer & Trust Company and the Registrant (incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 7, 2018). |
| 10.1 | Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.2 | Escrow Agreement, by and among Clene Inc., Fortis Advisors LLC and Continental Stock Transfer & Trust Company, as the escrow agent (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.3 | Form of Indemnification Agreement between the Registration and its directors and executive officers (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.4* | License Agreement, effective August 31, 2018, between Clene Nanomedicine, Inc. and 4Life Research, LLC (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.5* | Exclusive Supply Agreement, dated August 31, 2018, between Clene Nanomedicine, Inc. and 4Life Research, LLC (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.6* | Lease Agreement, dated May 9, 2016, and First Amendment of Lease Agreement, dated January 6, 2017, between Upper Chesapeake Flex One, LLC and Clene Nanomedicine, Inc. (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.7* | Clinical Research Support Agreement, dated September 27, 2019, between Clene Nanomedicine, Inc. and The General Hospital Corporation (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-4 filed by Chelsea Worldwide Inc. with the Securities and Exchange Commission on December 15, 2020). |
| 10.8** | 2020 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the registrant's Registration Statement on Form 8-K filed by the registrant on January 5, 2021). |
| 10.9 | Clene Inc. Board of Directors Compensation Program (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed by the registrant on April 22, 2021) |
| 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. |
| 101.1 | XBRL Instance Document |
| 101.2 | XBRL Taxonomy Extension Schema Document |
| 101.3 | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.4 | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.5 | XBRL Taxonomy Extension Label Linkbase Document |
| 101.6 | XBRL Taxonomy Extension Presentation Linkbase Document |

* Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

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

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: May 10, 2021

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

Dated: May 10, 2021

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

CERTIFICATION

I, Robert Etherington, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clene Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2021

/s/ Robert Etherington

Robert Etherington
Chief Executive Officer

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: May 10, 2021

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

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 March 31, 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: May 10, 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.

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 March 31, 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: May 10, 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.