

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

FORM 10-Q

(Mark One)

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

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

Or

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

For the transition period from _____ to _____

Commission file number: **001-34822**

ClearPoint Neuro, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

120 S. Sierra Ave., Suite 100
Solana Beach, California
(Address of Principal Executive Offices)

58-2394628
(IRS Employer
Identification Number)

92075
(Zip Code)

(888) 287-9109

(Registrant's Telephone Number, Including Area Code)

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, \$0.01 par value per share | CLPT | Nasdaq Capital Market |

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of November 9, 2021, there were 23,639,616 shares of common stock outstanding.

CLEARPOINT NEURO, INC.

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Trademarks, Trade Names and Service Marks

ClearPoint Neuro[®], *ClearPoint*[®], *ClearTrace*[®], *SmartFlow*[®], *SmartFrame*[®], *SmartGrid*[®], *Inflexion*[™], *SmartTwist*[™], *SmartTip*[™], *ClearPoint Pursuit*[®], *ClearPoint Maestro*[™], *ClearPoint Revolution*[™], *When Your Path is Unclear, We Point The Way*[™], and *MRI Interventions*[®] are all trademarks of ClearPoint Neuro, Inc. Any other trademarks, trade names or service marks referred to in this Quarterly Report on Form 10-Q (this “Quarterly Report”) are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains “forward-looking statements” as defined under the United States federal securities laws. The forward-looking statements are contained principally in the section of this Quarterly Report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements, expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the effects of the COVID-19 pandemic and measures taken or that may be taken by federal, state and local governmental authorities to combat the spread of the disease;
- future revenue from sales of ClearPoint system products and services; and
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

You should refer to the section titled “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, which we filed with the United States Securities and Exchange Commission (“SEC”) on March 22, 2021 (the “2020 Form 10-K”) and in this Quarterly Report, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by the forward-looking statements contained in this Quarterly Report. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this Quarterly Report, except to the extent required by applicable securities laws.

PART I – FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS**

CLEARPOINT NEURO, INC.
Condensed Consolidated Balance Sheets
(Dollars in thousands, except for per share data)

| | September 30, 2021 (Unaudited) | December 31, 2020 |
|---|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 57,651 | \$ 20,099 |
| Accounts receivable, net | 2,559 | 1,881 |
| Inventory, net | 3,943 | 3,238 |
| Prepaid expenses and other current assets | 842 | 244 |
| Total current assets | 64,995 | 25,462 |
| Property and equipment, net | 450 | 319 |
| Operating lease rights of use | 2,365 | 2,736 |
| Software license inventory | 519 | 589 |
| Licensing rights | 287 | 353 |
| Other assets | 86 | 59 |
| Total assets | <u>\$ 68,702</u> | <u>\$ 29,518</u> |
| LIABILITIES AND STOCKHOLDERS’ EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 777 | \$ 300 |
| Accrued compensation | 1,804 | 1,595 |

| | | |
|---|-----------|-----------|
| Other accrued liabilities | 1,081 | 349 |
| Operating lease liabilities, current portion | 486 | 394 |
| Deferred product and service revenue | 440 | 562 |
| Total current liabilities | 4,588 | 3,200 |
| Operating lease liabilities, net of current portion | 2,071 | 2,446 |
| Deferred product and service revenue, net of current portion | 310 | 215 |
| 2020 senior secured convertible notes payable, net | 17,613 | 21,280 |
| Total liabilities | 24,582 | 27,141 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2021 and December 31, 2020 | — | — |
| Common stock, \$0.01 par value; 200,000,000 shares authorized; 22,855,187 shares issued and outstanding at September 30, 2021; and 17,047,584 issued and outstanding at December 31, 2020 | 229 | 170 |
| Additional paid-in capital | 173,674 | 121,729 |
| Accumulated deficit | (129,783) | (119,522) |
| Total stockholders' equity | 44,120 | 2,377 |
| Total liabilities and stockholders' equity | \$ 68,702 | \$ 29,518 |

See accompanying notes to Condensed Consolidated Financial Statements.

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CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(Dollars in thousands, except for per share data)

| | For The Three Months Ended | |
|---|-----------------------------------|-------------|
| | September 30, | |
| | 2021 | 2020 |
| Revenue: | | |
| Product revenue | \$ 3,338 | \$ 2,371 |
| Service and other revenue | 1,236 | 1,148 |
| Total revenue | 4,574 | 3,519 |
| Cost of revenue | 1,486 | 903 |
| Gross profit | 3,088 | 2,616 |
| Research and development costs | 2,630 | 1,143 |
| Sales and marketing expenses | 1,826 | 1,493 |
| General and administrative expenses | 2,436 | 1,252 |
| Operating loss | (3,804) | (1,272) |
| Other expense: | | |
| Other income (expense), net | 62 | (11) |
| Interest expense, net | (238) | (201) |
| Net loss | \$ (3,980) | \$ (1,484) |
| Net loss per share attributable to common stockholders: | | |
| Basic and diluted | \$ (0.18) | \$ (0.09) |
| Weighted average shares used in computing net loss per share: | | |
| Basic and diluted | 22,522,460 | 15,724,401 |

| | For The Nine Months Ended | |
|---|----------------------------------|-------------|
| | September 30, | |
| | 2021 | 2020 |
| Revenues: | | |
| Product revenues | \$ 8,863 | \$ 6,186 |
| Service and other revenues | 3,154 | 2,927 |
| Total revenues | 12,017 | 9,113 |
| Cost of revenues | 4,015 | 2,636 |
| Gross profit | 8,002 | 6,477 |
| Research and development costs | 6,251 | 2,774 |
| Sales and marketing expenses | 5,081 | 3,916 |
| General and administrative expenses | 6,062 | 3,742 |
| Operating loss | (9,392) | (3,955) |
| Other income (expense): | | |
| Other (expense), net | (60) | (5) |
| Interest expense, net | (809) | (1,240) |
| Net loss | \$ (10,261) | \$ (5,200) |
| Net loss per share attributable to common stockholders: | | |
| Basic and diluted | \$ (0.50) | \$ (0.33) |
| Weighted average shares used in computing net loss per share: | | |
| Basic and diluted | 20,545,080 | 15,556,231 |

See accompanying notes to Condensed Consolidated Financial Statements.

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CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(Dollars in thousands)

For The Nine Months Ended September 30, 2021

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total |
|---|-------------------|---------------|----------------------------------|------------------------|------------------|
| | Shares | Amount | | | |
| Balance, January 1, 2021 | 17,047,584 | \$ 170 | \$ 121,729 | \$ (119,522) | \$ 2,377 |
| Adoption of ASU 2020-06 | — | — | (3,107) | — | (3,107) |
| Issuances of common stock: | | | | | |
| Public offering of common stock | 2,127,660 | 21 | 46,764 | — | 46,785 |
| Share-based compensation | 20,709 | 1 | 319 | — | 320 |
| Warrant and option exercises (cash and cashless) | 1,482,327 | 15 | 130 | — | 145 |
| Net loss for the period | — | — | — | (2,538) | (2,538) |
| Balance, March 31, 2021 | 20,678,280 | \$ 207 | \$ 165,835 | \$ (122,060) | \$ 43,982 |
| Conversion of 2020 senior secured convertible note | 1,256,143 | 13 | 7,118 | — | 7,131 |
| Issuances of common stock: | | | | | |
| Share-based compensation | 26,435 | — | 247 | — | 247 |
| Warrant and option exercises (cash and cashless) | 361,486 | 3 | 346 | — | 349 |
| Net loss for the period | — | — | — | (3,743) | (3,743) |
| Balance, June 30, 2021 | 22,322,344 | \$ 223 | \$ 173,546 | \$ (125,803) | \$ 47,966 |
| Issuances of common stock: | | | | | |
| Share-based compensation | 126,805 | 1 | 585 | — | 586 |
| Warrant and option exercises (cash and cashless) | 435,802 | 5 | 85 | — | 90 |
| Payments for taxes related to net share settlement of equity awards | (29,764) | — | (542) | — | (542) |
| Net loss for the period | — | — | — | (3,980) | (3,980) |
| Balance, September 30, 2021 | <u>22,855,187</u> | <u>\$ 229</u> | <u>\$ 173,674</u> | <u>\$ (129,783)</u> | <u>\$ 44,120</u> |

For The Nine Months Ended September 30, 2020

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total |
|------------------------------|-------------------|---------------|----------------------------------|------------------------|---------------|
| | Shares | Amount | | | |
| Balance, January 1, 2020 | 15,235,308 | \$ 152 | \$ 117,174 | \$ (112,740) | \$ 4,586 |
| Issuances of common stock: | | | | | |
| Share-based compensation | 9,696 | — | 228 | — | 228 |
| Warrant exercises (cashless) | 262,145 | 3 | (3) | — | — |
| Net loss for the period | — | — | — | (2,055) | (2,055) |
| Balance, March 31, 2020 | 15,507,149 | \$ 155 | \$ 117,399 | \$ (114,795) | \$ 2,759 |
| Issuances of common stock: | | | | | |
| Share-based compensation | 5,538 | — | 241 | — | 241 |
| Net loss for the period | — | — | — | (1,661) | (1,661) |
| Balance, June 30, 2020 | 15,512,687 | \$ 155 | \$ 117,640 | \$ (116,456) | \$ 1,339 |
| Issuances of common stock: | | | | | |
| Share-based compensation | 248,637 | 3 | 291 | — | 294 |
| Warrant exercises (cashless) | 120,080 | 1 | (1) | — | — |
| Net loss for the period | — | — | — | (1,484) | (1,484) |
| Balance, September 30, 2020 | <u>15,881,404</u> | <u>\$ 159</u> | <u>\$ 117,930</u> | <u>\$ (117,940)</u> | <u>\$ 149</u> |

See accompanying notes to Condensed Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(Dollars in thousands)

| | For The Nine Months Ended September 30, | |
|--|--|------------|
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Net loss | \$ (10,261) | \$ (5,200) |
| Adjustments to reconcile net loss to net cash flows from operating activities: | | |
| Allowance for doubtful accounts | 170 | 13 |
| Depreciation and amortization | 113 | 170 |
| Share-based compensation | 1,153 | 762 |
| Payment-in-kind interest | 285 | — |
| Amortization of debt issuance costs and original issue discounts | 73 | 856 |
| Amortization of lease rights of use, net of accretion in lease liabilities | 400 | 75 |
| Increase (decrease) in cash resulting from changes in: | | |
| Accounts receivable | (848) | (373) |
| Inventory, net | (682) | (323) |
| Prepaid expenses and other current assets | (599) | (136) |
| Other assets | (28) | 59 |

| | | |
|--|------------------|------------------|
| Accounts payable and accrued expenses | 1,418 | 60 |
| Accrued interest | — | (960) |
| Lease liabilities | (312) | (71) |
| Deferred revenue | (27) | (338) |
| Net cash flows from operating activities | <u>(9,145)</u> | <u>(5,406)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (130) | — |
| Acquisition of licensing rights | — | (441) |
| Net cash flows from investing activities | <u>(130)</u> | <u>(441)</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount | — | 16,758 |
| Proceeds from issuance of Paycheck Protection Program loan | — | 896 |
| Proceeds from public offering of common stock, net of offering costs | 46,785 | — |
| Proceeds from stock option and warrant exercises | 584 | — |
| Payments for taxes related to net share settlement of equity awards | (542) | — |
| Repayment of notes payable | — | (2,838) |
| Net cash flows from financing activities | <u>46,827</u> | <u>14,816</u> |
| Net change in cash and cash equivalents | 37,552 | 8,969 |
| Cash and cash equivalents, beginning of period | 20,099 | 5,696 |
| Cash and cash equivalents, end of period | <u>\$ 57,651</u> | <u>\$ 14,665</u> |

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:

| | | |
|--------------|--------|----------|
| Income taxes | \$ — | \$ — |
| Interest | \$ 495 | \$ 1,399 |

NON-CASH TRANSACTIONS:

- During the nine months ended September 30, 2021 and 2020, the Company recorded net transfers to inventory of ClearPoint reusable components having an aggregate net book value of \$0.03 million and \$0.04 million, respectively, from loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets.
- As discussed in Note 2, on January 1, 2021, the Company adopted the provisions of Topic 470-20 within the Accounting Standards Codification, which resulted in the elimination of a previously recorded discount in connection with the issuance of the 2020 Secured Notes and a corresponding reduction of additional paid-in capital, each in the amount of \$3.1 million.
- As discussed in Note 5, in May 2021, one of the 2020 Convertible Noteholders converted the entire \$7.5 million principal amount of its First Closing Note, and related accrued interest amounting to approximately \$0.04 million, into 1,256,143 shares of the Company's common stock. As a result, the discount on such First Closing Note, amounting to \$0.2 million at the conversion date and representing an access fee paid to the noteholder at origination of such First Closing Note, was eliminated and a corresponding amount was charged to additional paid-in capital upon the conversion.

See accompanying notes to Condensed Consolidated Financial Statements.

ClearPoint Neuro, Inc. Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Description of the Business and Financial Condition

ClearPoint Neuro, Inc. (the "Company") is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain using direct, intra-procedural magnetic resonance imaging ("MRI") guidance while performing minimally invasive surgical procedures.

The Company's ClearPoint system, an integrated system comprised of capital equipment and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2010 to market the ClearPoint system in the United States for general neurological interventional procedures.

COVID-19

In March 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and the President of the United States later proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Extraordinary actions were taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuances of "stay-at-home" directives and similar mandates that substantially restricted daily activities and for many businesses curtailed or ceased normal operations. These measures led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using the Company's ClearPoint system. Although economic activity is returning to a normalized level, the Delta variant of COVID-19 continues to spread in the United States and across the globe. The ultimate impact of the Delta variant, and other new strains that may develop, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Delta and other variants and the response by governmental bodies and regulators, which could include vaccine mandates.

Furthermore, global supply chain disruptions, labor shortages, which may affect our ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic could have a material adverse effect on the Company's business. The rapid development and fluidity of the situation preclude any prediction as to the ultimate impact COVID-19 will have on the Company's business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States and globally.

Liquidity

The Company has incurred net losses since its inception, which has resulted in a cumulative deficit at September 30, 2021 of approximately \$30 million. In addition, the Company's use of cash from operations amounted to \$9.1 million for the nine months ended September 30, 2021 and \$7.8 million for the year ended December 31, 2020. Since its inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable, product and service contracts and license arrangements.

In January 2020, the Company entered into a Securities Purchase Agreement (the “SPA”) with two investors (each, a “2020 Convertible Noteholder,” and together, the “2020 Convertible Noteholders”) under which the Company issued an aggregate principal amount of \$17.5 million of floating rate secured convertible notes with a five year term (the “First Closing Notes”), resulting in proceeds, net of financing costs, and a commitment fee paid to one of the 2020 Convertible Noteholders, of approximately \$16.8 million. In the first quarter of 2020, the Company used \$3.7 million from the net proceeds received from the issuance of the First Closing Notes to repay and retire the 2010 Junior Secured Notes Payable (the “2010 Secured Notes”) that otherwise would have matured in October and November 2020.

The SPA also gave the Company the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase an additional \$5.0 million in principal amount of a note (the “Second Closing Note”, and, together with the First Closing Note, the “2020 Secured Notes”). On December 29, 2020, under the terms of an amendment to the SPA (the “Amendment”) which, among other provisions, increased the principal amount of the Second Closing Note to \$7.5 million.

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

See Note 5 for additional information with respect to the 2020 Secured Notes.

In April 2020, the Company received \$0.9 million in proceeds through a loan funded under the Paycheck Protection Program as part of the CARES Act (the “PPP Loan”). In November 2020, the Company was notified by the U.S. Small Business Administration that the loan had been forgiven under the provision of the CARES Act.

As discussed in Note 7, on February 23, 2021, the Company completed a public offering of 2,127,660 shares of its common stock. Net proceeds from the offering were approximately \$46.8 million after deducting the underwriting discounts and commissions and other estimated offering expenses payable by the Company.

Based on the foregoing, in management’s opinion, cash and cash equivalent balances at September 30, 2021, are sufficient to support the Company’s operations and meet its obligations for at least the next twelve months.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

In the opinion of management, the accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company’s December 31, 2020 audited consolidated financial statements, and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth therein. These condensed consolidated financial statements have been prepared in accordance with SEC rules for interim financial information, and, therefore, omit certain information and footnote disclosures necessary to present such statements in accordance with generally accepted accounting principles in the U.S. (“GAAP”). The preparation of these condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2020 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2020 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three and nine months ended September 30, 2021 may not be indicative of the results to be expected for the entire year or any future periods.

Inventory

Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. Items in inventory relate predominantly to the Company’s ClearPoint system. Software license inventory related to ClearPoint systems undergoing on-site customer evaluation is included in inventory in the accompanying condensed consolidated balance sheets. All other software license inventory is classified as a non-current asset. The Company periodically reviews its inventory for obsolete items and provides a reserve upon identification of potentially obsolete items.

Intangible Assets

The Company is a party to certain license agreements that provide rights to the Company for the development and commercialization of products. Under the terms of those license agreements, the Company made payments to the licensors upon execution of the license agreements for access to the underlying technologies and will make future payments based on the achievement of regulatory and commercialization milestones as defined in the license agreements.

In conformity with Accounting Standards Codification Section 350, “Intangibles – Goodwill and Other,” the Company amortizes its investment in the license rights described above over an expected useful life of five years. In addition, the Company periodically evaluates the recoverability of its investment in the license rights and records an impairment charge in the event such evaluation indicates that the Company’s investment is not likely to be recovered.

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Revenue Recognition

The Company’s revenue is comprised primarily of: (1) product revenue resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenue resulting from the sale of ClearPoint capital equipment and software; (3) revenue resulting from the service, installation, training and shipping related to ClearPoint capital equipment and software; and (4) consultation and clinical case support revenue in connection with customer-sponsored clinical trials. The Company recognizes revenue when control of the Company’s products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services, in a process that involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. When a contract calls for the satisfaction of multiple performance obligations for a single contract price, the Company allocates the contract price among the performance obligations based on the relative stand-alone prices for each such performance obligation customarily charged by the Company. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the

good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Lines of Business; Timing of Revenue Recognition

- *Functional neurosurgery navigation product, biologics and drug delivery systems product, and therapy product sales:* Revenue from the sale of functional neurosurgery navigation products (consisting of disposable products sold commercially and related to cases utilizing the Company's ClearPoint system), biologics and drug delivery systems (consisting primarily of disposable products related to customer-sponsored clinical trials utilizing the ClearPoint system), and therapy products (consisting primarily of disposable laser-related products used in non-neurosurgical procedures), is generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and are recognized at the point in time of delivery to the customer, which is the point at which legal title, and risks and rewards of ownership, along with physical possession, transfer to the customer.
- *Capital equipment and software sales*
 - *Capital equipment and software sales preceded by evaluation periods:* The predominance of capital equipment and software sales (consisting of integrated computer hardware and software that are integral components of the Company's ClearPoint system) are preceded by customer evaluation periods. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, revenue from capital equipment and software sales following such evaluation periods is recognized at the point in time the Company is in receipt of an executed purchase agreement or purchase order.
 - *Capital equipment and software sales not preceded by evaluation periods:* Revenue from sales of capital equipment and software not having been preceded by an evaluation period is recognized at the point in time that the equipment has been delivered to the customer.

For both types of capital equipment and software sales described above, the Company's determination of the point in time at which to recognize revenue represents that point at which the customer has legal title, physical possession, and the risks and rewards of ownership, and the Company has a present right to payment.

- *Functional neurosurgery navigation and therapy services:* The Company recognizes revenue for such services at the point in time that the performance obligation has been satisfied.

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ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

- *Biologics and drug delivery services:*
 - *Consultation Services:* The Company recognizes consultation revenue at the point in time such services are performed.
 - *Clinical Service Access Fees:* For contracts in which the Company receives a periodic fixed fee, irrespective of the number of cases attended by Company personnel during such periods, revenue is recognized ratably over the period covered by such fees. A time-elapsed output method is used for such fees because the Company transfers control evenly by providing a stand-ready service.
 - *Clinical Service Procedure-Based Fees:* The Company recognizes revenue at the point in time a case is attended by Company personnel.
- *Capital equipment-related services:*
 - *Equipment service:* Revenue from service of ClearPoint capital equipment and software previously sold to customers is based on agreements with terms ranging from one to three years and revenue is recognized ratably on a monthly basis over the term of the service agreement. A time-elapsed output method is used for service revenue because the Company transfers control evenly by providing a stand-ready service.
 - *Installation, training and shipping:* Consistent with the Company's recognition of revenue for capital equipment and software sales as described above, fees for installation, training and shipping in connection with sales of capital equipment and software that have been preceded by customer evaluation periods are recognized as revenue at the point in time the Company is in receipt of an executed purchase order for the equipment and software. Installation, training and shipping fees related to capital equipment and software sales not having been preceded by an evaluation period are recognized as revenue at the point in time that the related services are performed.

The Company operates in one industry segment, and substantially all its sales are to U.S.-based customers.

Payment terms under contracts with customers generally are in a range of 30-60 days after the customers' receipt of the Company's invoices.

The Company's terms and conditions do not provide for a right of return unless for: (a) product defects; or (b) other conditions subject to the Company's approval.

See Note 3 for additional information regarding revenue recognition.

Net Loss Per Share

The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Basic and diluted net loss per share are the same because the conversion, exercise or issuance of all potential common stock equivalents, which comprise the entire amount of the Company's outstanding common stock options and warrants, as described in Note 7, and the potential conversion of the First and Second Closing Notes, as described in Note 5, would be anti-dilutive, due to the reporting of a net loss for each of the periods in the accompanying condensed consolidated statements of operations.

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Concentration Risks and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company holds substantially all its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At September 30, 2021, the Company had approximately \$52 million in bank balances that were in excess of the insured limits.

At September 30, 2021, there were no customers whose accounts receivable balance exceeded 10% of accounts receivable at that date. At December 31, 2020, one customer accounted for 11% of accounts receivable at that date.

One customer, a related party as discussed in Note 3, accounted for 18% and 15% of total sales in the three-month periods ended September 30, 2021 and 2020, respectively, and for 19% and 18% of total sales in the nine-month periods ended September 30, 2021 and 2020, respectively.

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts at September 30, 2021 and December 31, 2020 was \$0.2 million and \$0.06 million, respectively.

The Company is subject to risks common to emerging companies in the medical device industry, including, but not limited to: new technological innovations; acceptance and competitiveness of its products; dependence on key personnel; dependence on key suppliers; dependence on third-party collaboration, license and joint development partners; changes in general economic conditions and interest rates; protection of proprietary technology; compliance with changing government regulations; uncertainty of widespread market acceptance of products; access to credit for capital purchases by customers; and product liability claims. Certain components used in manufacturing have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

Adoption of New Accounting Standard

Effective January 1, 2021, the Company adopted, on a modified retrospective method of transition, the provisions of Accounting Standards Update No. 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) – Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" (the "ASU"). The ASU is effective for public companies, other than smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, and for smaller reporting companies, which is the Company's current classification, for fiscal years beginning after December 31, 2023. However, the ASU permits early adoption, no earlier than for fiscal years beginning after December 31, 2020, and the Company elected such early adoption. The ASU amends prior authoritative literature to reduce the number of accounting models for, among others, convertible debt instruments for which the embedded conversion features of such instruments had previously been required to be separated from the host contract. The Company determined that the conversion feature embedded in the Second Closing Note (see Note 5) was within the scope of the ASU. Accordingly, the discount originally recorded in connection with the issuance of the Second Closing Note and a corresponding amount recorded in additional paid-in capital, each in the amount of approximately \$3.1 million at the date of issuance of the Second Closing Note, were reversed as of the date of adoption of the ASU.

Reclassifications

The accompanying consolidated statements of operations for the three and nine months ended September 30, 2021 contain: (a) certain items formerly classified as service revenue that have been reclassified to product revenue; (b) certain items formerly classified as general and administrative expenses, research and development expenses, and sales and marketing expenses that have been reclassified to cost of revenue; and (c) an item formerly classified as interest expense that has been reclassified as other expense. The accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2020 have been conformed to the 2021 presentation.

ClearPoint Neuro, Inc. Notes to Condensed Consolidated Financial Statements (Unaudited)

3. Revenue Recognition

Revenue by Service Line

| (in thousands) | Three Months Ended September 30, | |
|---|----------------------------------|----------|
| | 2021 | 2020 |
| Functional neurosurgery navigation and therapy | | |
| Disposable products | \$ 2,004 | \$ 1,840 |
| Services | 150 | — |
| Subtotal – functional neurosurgery navigation and therapy | 2,154 | 1,840 |
| Biologics and drug delivery | | |
| Disposable products | 1,137 | 420 |
| Services | 920 | 1,055 |
| Subtotal – biologics and drug delivery | 2,057 | 1,475 |
| Capital equipment and software | | |
| Systems and software products | 197 | 111 |
| Services | 166 | 93 |
| Subtotal – capital equipment and software | 363 | 204 |
| Total revenue | \$ 4,574 | \$ 3,519 |

| (in thousands) | Nine Months Ended September 30, | |
|--|---------------------------------|----------|
| | 2021 | 2020 |
| Functional neurosurgery navigation and therapy | | |
| Disposable products | \$ 5,782 | \$ 4,652 |
| Services | 150 | — |

| | | |
|---|------------------|-----------------|
| Subtotal – functional neurosurgery navigation and therapy | 5,932 | 4,652 |
| Biologics and drug delivery | | |
| Disposable products | 2,501 | 1,000 |
| Services | 2,605 | 2,671 |
| Subtotal – biologics and drug delivery | 5,106 | 3,671 |
| Capital equipment and software | | |
| Systems and software products | 580 | 534 |
| Services | 399 | 256 |
| Subtotal – capital equipment and software | 979 | 790 |
| Total revenue | <u>\$ 12,017</u> | <u>\$ 9,113</u> |

Contract Balances

- *Contract assets* – Substantially all the Company’s contracts with customers are based on customer-issued purchase orders for distinct products or services. Customers are billed upon delivery of such products or services, and the related contract assets comprise the accounts receivable balances included in the accompanying condensed consolidated balance sheets.
- *Contract liabilities* – The Company generally bills and collects capital equipment and software-related service fees at the inception of the service agreements, which have terms ranging from one to three years. The unearned portion of such service fees is classified as deferred revenue.

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ClearPoint Neuro, Inc. **Notes to Condensed Consolidated Financial Statements** **(Unaudited)**

During the three and nine months ended September 30, 2021, the Company recognized capital equipment and software-related service revenue of approximately \$0.1 million and \$0.3 million, respectively, which were previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2020.

In 2019, the Company entered into a Development Services Agreement with a customer under which the Company was entitled to bill the customer for an upfront payment of \$0.13 million, of which approximately \$0.02 million and \$0.05 million are included in deferred revenue in the accompanying condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020, respectively.

Commencing in 2019, the Company was a party to a Letter of Intent and a related Statement of Work (together with the Letter of Intent, the “Project Documents”) with a customer who is a stockholder and a noteholder (see Note 5), and an officer of whom is a member of the Company’s Board of Directors, to commence a product development project. Under the terms of the Project Documents, the Company was entitled to bill the customer for: (a) an upfront, nonrefundable payment of \$0.5 million, which was received in 2019; and (b) quarterly service fees of \$0.5 million. In February 2020, the Company entered into a Supply Agreement and a Statement of Work (the “European SOW”) with a European affiliate of the customer. Under the terms of the European SOW, the Company was entitled to bill the customer on a quarterly basis, commencing in the first quarter of 2020, for service fees of \$0.25 million. During 2020, the clinical trials contemplated by the Project Documents and the European SOW were delayed as a result of the COVID-19 pandemic. As a result, the Company agreed to reduce such quarterly service fees by an aggregate of \$0.25 million through September 30, 2020. In November 2020, the Company entered into an addendum to the Project Documents and the European SOW that, among other provisions, set the aggregate service fee to be billed to the customer at \$0.7 million per quarter, effective October 1, 2020. The Company recognized as revenue the upfront payment described in this paragraph ratably over the initial two years of the term of the Project Documents, corresponding to the estimated period in which the related performance obligations were expected to be satisfied, and recognizes as revenue the quarterly service fees described in this paragraph as stand-by services beginning in the quarter such services commenced. Based on the foregoing: (a) the Company recognized revenue of approximately \$0.7 million and \$2.1 million for the three and nine months ended September 30, 2021, respectively; (b) accounts receivable from the customer amounted to approximately \$0.1 million at each of September 30, 2021 and December 31, 2020; and (c) the aggregate amount of all the payments described in this paragraph that were included in deferred revenue in the accompanying condensed consolidated balance sheets at September 30, 2021 and December 31, 2020, were nil and approximately \$0.1 million, respectively.

The Company offers an upgraded version of its software at no additional charge to customers purchasing a three-year systems service agreement. The transaction prices of the software and the service agreement are determined through an allocation of the service agreement price based on the standalone prices of the software and the service agreements customarily charged by the Company. The transaction price of the software is recognized as revenue upon its installation and comprised less than \$0.1 million of unbilled receivable at September 30, 2021 and \$0.1 million at December 31, 2020.

Remaining Performance Obligations

The Company’s contracts with customers for functional neurosurgery and therapy product sales are predominantly of terms less than one year. Accordingly, the transaction prices of remaining performance obligations related to such contracts at September 30, 2021 are not material.

Revenue with respect to remaining performance obligations related to capital equipment and software-related service agreements with original terms in excess of one year and the upfront payments discussed under the heading “Contract Balances” above amounted to approximately \$0.8 million at September 30, 2021. The Company expects to recognize this revenue within the next three years.

Revenue with respect to remaining performance obligations related to contracts with the Company’s biologic and drug delivery customers, other than those contracts discussed under the heading “Contract Balances,” predominantly is contingent upon such customers’ performance of clinical trials on which the Company’s performance obligations are predicated.

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ClearPoint Neuro, Inc. **Notes to Condensed Consolidated Financial Statements** **(Unaudited)**

4. Inventory

Inventory consists of the following as of:

| <i>(in thousands)</i> | September 30, 2021 | December 31, 2020 |
|--|-----------------------|----------------------|
| Raw materials and work in process | \$ 2,314 | \$ 1,485 |
| Software licenses | 210 | 193 |
| Finished goods | 1,419 | 1,560 |
| Inventory, net, included in current assets | 3,943 | 3,238 |
| Software licenses – non-current | 519 | 589 |
| Total | <u>\$ 4,462</u> | <u>\$ 3,827</u> |

5. Notes Payable

As a result of the transactions described below, an aggregate principal amount of \$17.5 million of the 2020 Secured Convertible Notes was outstanding at September 30, 2021. At the option of the holders at any time prior to maturity, \$10 million in principal amount of the 2020 Secured Convertible Notes, which are held by a customer who is a stockholder and has a representative on the Company's Board of Directors, are convertible to the Company's common stock at a conversion price of \$6.00, and \$7.5 million in principal amount of the 2020 Secured Convertible Notes are convertible at a price of \$10.14, subject in both cases to adjustments as set forth in the SPA and the note agreements.

On January 29, 2020 (the "Closing Date"), the Company completed a financing transaction (the "2020 Financing Transaction") with the 2020 Convertible Noteholders, whereby the Company issued an aggregate principal amount of \$17.5 million of First Closing Notes pursuant to the SPA dated January 11, 2020, which, unless earlier converted or redeemed, mature on the fifth anniversary of the Closing Date and bear interest at a rate equal to the sum of (i) the greater of (a) the three (3)-month London Interbank Offered Rate ("LIBOR") and (b) two percent (2%), plus (ii) a margin of 2% on the outstanding balance of the First Closing Notes, payable quarterly on the first business day of each calendar quarter. The First Closing Notes may be converted at a price of \$6.00 per share, subject to certain adjustments set forth in the SPA, and may not be pre-paid without the consent of the noteholder, provided that the Company must offer to pre-pay such other noteholder on the same terms and conditions.

In May 2021, one of 2020 Convertible Noteholders (the "Converting Noteholder") converted the entire \$7.5 million principal amount of such Converting Noteholder's First Closing Note, and related accrued interest, amounting to approximately \$0.04 million, into 1,256,143 shares of the Company's common stock.

At the Closing Date, the SPA gave the Company the right, but not the obligation, to request at any time on or prior to January 11, 2022, that one of the 2020 Convertible Noteholders purchase an additional \$5.0 million in aggregate principal amount of Second Closing Note and an additional \$10.0 million in aggregate principal amount of Third Closing Note (as defined in the SPA; together, with the Second Closing Note, the "Additional Convertible Notes"), provided that such 2020 Convertible Noteholder has the right, but not the obligation, to purchase such notes. The Additional Convertible Notes would also mature on the fifth anniversary of the Closing Date.

On December 29, 2020, the Company and the 2020 Convertible Noteholders entered into the Amendment to the SPA, the terms of which, among other provisions, provided for: (a) an increase in the principal amount of the Second Closing Note to \$7.5 million; (b) a revision of the interest rate to be borne by the Second Closing Note to consist of: (i) cash interest of 2% per annum, payable quarterly; and (ii) payment-in-kind interest of 5% per annum, accruable quarterly as an addition to the unpaid principal balance of the Second Closing Note; and (c) an increase in the conversion price of the Second Closing Notes to \$10.14 per share, subject to certain adjustments set forth in the SPA. Upon execution of the Amendment, the Company issued the Second Closing Note.

ClearPoint Neuro, Inc. Notes to Condensed Consolidated Financial Statements (Unaudited)

The aggregate carrying amounts of the First Closing Notes in the accompanying September 30, 2021 and December 31, 2020 condensed consolidated balance sheets are presented net of financing costs, comprised of commissions and legal expenses, having an unamortized balance of \$0.2 million and \$0.4 million at those respective dates. In addition, the aggregate carrying amount of the First Closing Note in the accompanying December 31, 2020 condensed consolidated balance sheet is presented net of a discount, comprised of a commitment fee paid to the Converting Noteholder, amounting to \$0.2 million. Upon conversion of the related note, the discount, amounting to \$0.2 million at the date of conversion, was reversed, with a corresponding amount being recorded as a reduction of additional paid-in capital. The unamortized balances of the financing costs and the discount, during the period prior to the conversion of the related First Closing Note, are charged to interest expense over the respective terms of the First Closing Notes under the effective interest method.

The carrying amount of the Second Closing Note in the accompanying December 31, 2020 consolidated balance sheet is presented net of a discount, amounting to approximately \$3.1 million at December 31, 2020, and representing the value of the deemed beneficial conversion feature embedded in the Second Closing Note. A beneficial conversion feature is deemed to be beneficial when the conversion price, discussed above, is lower than the closing price per share of the Company's common stock, which was \$14.34 on the date of issuance of the Second Closing Note. Under GAAP in existence at the date of issuance of the Second Closing Note, the resulting discount was calculated as the product of (i) the number of shares into which the Second Closing Note could be converted, multiplied by (ii) the difference between the closing price per share and the conversion price. Upon recordation of the discount, a corresponding amount was added to additional paid-in capital. As discussed in Note 2, effective January 1, 2021, the Company adopted the provisions of the ASU that no longer required such beneficial conversion features to be separately accounted for as previously described in this paragraph. As a result, the accompanying September 30, 2021 condensed consolidated balance sheet reflects the elimination of both the discount and the corresponding increase to additional paid-in capital previously described in this paragraph.

Under the terms of the SPA, as amended, the Company retains the right, but not the obligation, to request the 2020 Convertible Noteholder to purchase the Third Closing Note, and the 2020 Convertible Noteholder has the right, but not the obligation, to purchase such note. As of September 30, 2021, the Company had not made such a request.

The 2020 Secured Notes are secured by all the assets of the Company.

An executive officer of one of the 2020 Convertible Noteholders is a member of the Company's Board of Directors. Pursuant to the terms of the SPA and a Board Observer Agreement entered into by the other 2020 Convertible Noteholder and the Company, the other 2020 Convertible Noteholder appointed a representative to attend and observe meetings of the Company's Board of Directors. On February 25, 2021, such 2020 Convertible Noteholder terminated the Board Observer Agreement, thus precluding its representative from attending future meetings of the Company's Board of Directors.

On January 27, 2020, as a condition to completion of the 2020 Financing Transaction, the Company entered into the Fourth Omnibus Amendment to the 2010 Secured Notes, whereby the 2010 Secured Notes were subordinated to the Company's obligations under the terms of the 2020 Secured Notes and the Additional Convertible Notes, as applicable. During the first fiscal quarter of 2020, the Company repaid in full the aggregate outstanding principal amount of the 2010 Secured Notes, amounting to approximately \$2.8 million, which, along with the Company's payment of accrued interest amounting to approximately \$0.9 million, resulted in the full retirement of the 2010 Secured Notes.

Scheduled principal payments as of September 30, 2021 with respect to notes payable are summarized as follows:

| Year ending December 31, 2025 | <i>(in thousands)</i> |
|------------------------------------|-----------------------|
| Total scheduled principal payments | \$ 17,788 |
| Less: Unamortized financing costs | 17,788 |
| Total | <u>(175)</u> |
| | <u>\$ 17,613</u> |

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

6. Leases

The Company leases office space in Irvine, California that houses office space and a manufacturing facility under a non-cancellable operating lease. The lease term commenced on October 1, 2018 and expires in September 2023. The Company has the option to renew the lease for two additional periods of five years each. The Company also leases office space in Solana Beach, California that houses certain management, and research and development personnel, and serves as its corporate headquarters. The lease term commenced on December 15, 2020, is set to expire on December 31, 2026, and is renewable for an additional five-year period, at the Company's option, provided that the Company's landlord has entered into an extension of its lease for the office space that encompasses the Company's office space for at least five years. Both office leases are classified as operating leases in conformity with GAAP.

The lease cost, included in general and administrative expense, was \$0.1 million and \$0.03 million for the three months ended September 30, 2021 and 2020, respectively, and was \$0.4 million and \$0.1 million for the nine months ended September 30, 2021 and 2020, respectively.

7. Stockholders' Equity

2021 Public Offering

On February 23, 2021, the Company completed a public offering of 2,127,660 shares of its common stock, composed of 1,850,140 shares of common stock initially offered at a public offering price of \$23.50 per share and an additional 277,520 shares of common stock sold pursuant to the exercise of the underwriters' option to purchase additional shares at the price of \$22.09 per share.

Net proceeds from the offering totaled approximately \$46.8 million after deducting underwriting discounts and commissions, and other offering expenses paid by the Company.

The underwriting agreement contains representations, warranties, agreements and indemnification obligations by the Company that are customary for this type of transaction.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each compensated non-employee member of the Company's Board of Directors may elect to receive all or part of his or her director fees in shares of the Company's common stock. Effective from June 25, 2021, director fees, whether paid in cash or in shares of common stock, are payable quarterly on the first business day following the end of the quarter. The number of shares of common stock issued to directors is determined by dividing the product of: (i) (a) the fees otherwise payable to each director in cash, times (b) the percentage of fees the director elected to receive in shares of common stock, by (ii) the volume weighted average price per share of common stock over the last five trading days of the quarter. The following is information regarding the number of shares issued to directors as payment for director fees in lieu of cash for the three and nine months ended September 30, 2021 and 2020:

| <u>Three Months Ended September 30,</u> | |
|---|-------------|
| <u>2021</u> | <u>2020</u> |
| — | 6,141 |
| <u>Nine Months Ended September 30,</u> | |
| <u>2021</u> | <u>2020</u> |
| 3,829 | 25,704 |

Stock Incentive Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, the "Plans") under which it has granted share-based awards, such as stock grants, and incentive and non-qualified stock options, to employees, directors, consultants and advisors. Awards may be subject to a vesting schedule as set forth in individual award agreements.

ClearPoint Neuro, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

From October 2017 until June 2020, the Company granted share-based awards under the Company's Second Amended and Restated 2013 Incentive Compensation Plan (the "Second Amended Plan"). On June 2, 2020, the Company's stockholders approved the Company's Third Amended and Restated 2013 Incentive Compensation Plan (the "Third Amended Plan" and, together with the Second Amended Plan, the "2013 Plan"), under which 1.0 million shares of the Company's common stock were made available for future issuances under the 2013 Plan, resulting in a total of 2,956,250 shares of the Company's common stock being reserved for issuance under the 2013 Plan. Of this amount, stock grants of 834,060 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 1,378,400 shares were outstanding as of September 30, 2021. Accordingly, 743,790 shares remained available for grants under the 2013 Plan as of that date.

Stock option activity under all of the Company's Plans and share-based compensatory contracts during the nine months ended September 30, 2021 is summarized below:

| | Option Shares | Weighted- average Exercise price per share | Intrinsic Value ⁽¹⁾ (in thousands) |
|-----------------------------------|------------------|---|---|
| Outstanding at January 1, 2021 | 1,806,092 | \$ 7.12 | \$ 20,760 |
| Granted | 121,703 | 18.12 | |
| Exercised | (557,184) | 2.69 | |
| Expired / terminated | (18,500) | 20.46 | |
| Outstanding at September 30, 2021 | 1,352,111 | \$ 9.75 | \$ 15,328 |

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at the end of the related period less the option exercise price of in-the-money options.

As of September 30, 2021, there was unrecognized compensation expense of approximately \$4.8 million related to outstanding stock options and shares of restricted stock, which is expected to be recognized over a weighted average period of 2.3 years.

ESPP

On June 3, 2021, the Company's stockholders adopted and approved the ClearPoint Neuro, Inc. Employee Stock Purchase Plan (the "ESPP"), which allows eligible employees to acquire shares of the Company's common stock through payroll deductions at a discount to market price. A total of 400,000 shares of the Company's common stock are available for issuance pursuant to the terms of the ESPP. The initial six-month purchase period commenced in July 2021, and accordingly, no shares have been sold under the ESPP.

Warrants

Warrants to purchase shares of the Company's common stock were issued in connection with financing transactions in 2015, 2016, and 2017, and are generally for terms of five years. These warrants contain net exercise provisions giving the holder the option of acquiring a number of shares having a value equal to the difference between the exercise price and the current stock price, in lieu of paying the exercise price to acquire the full number of stated shares. All of the warrants outstanding at September 30, 2021 will terminate by the year end 2023.

Common stock warrant activity for the nine months ended September 30, 2021 was as follows:

| | Warrant Shares | Weighted-average Exercise price per share | Intrinsic Value ⁽¹⁾ (in thousands) |
|-----------------------------------|-------------------|---|---|
| Outstanding at January 1, 2021 | 3,082,987 | \$ 3.82 | \$ 37,379 |
| Exercised | (2,023,190) | 3.31 | |
| Terminated | (390,390) | 7.78 | |
| Outstanding at September 30, 2021 | 669,407 | \$ 2.97 | \$ 9,895 |

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at the end of the related period less the option exercise price of in-the-money options.

8. Subsequent Events

On November 3, 2021, the holder of the Second Closing Note (see Note 5) converted the entire \$7.8 million principal amount of such note, along with related accrued and payment-in-kind interest aggregating \$0.05 million, into 773,446 shares of the Company's common stock.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and the related notes thereto appearing in Part I, Item 1 of this Quarterly Report. This discussion and analysis contains forward-looking statements that are based upon current expectations and involve risks, assumptions and uncertainties. You should review the section titled "Risk Factors" appearing in our 2020 Form 10-K and in Part II, Item 1.A of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis. In addition, historical results and trends that might appear in this Quarterly Report should not be interpreted as being indicative of future operations.

Overview

We are a medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain under direct, intra-procedural MRI guidance. Our principal product platform is our ClearPoint system, which is in commercial use and is used to perform minimally invasive surgical procedures in the brain. The ClearPoint system utilizes intra-procedural MRI to guide the procedures and is designed to work in a hospital's existing MRI suite. We believe that this product platform delivers better patient outcomes, enhances revenue potential for both physicians and hospitals, and reduces costs to the healthcare system.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the U.S. for general neurosurgery procedures. In 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. Substantially all our product revenue for the three and nine months ended September 30, 2021 and 2020 relates to sales of our ClearPoint system products and related services. We have financed our operations and internal growth primarily through the sale of equity securities, the issuance of convertible and other secured notes, and license arrangements. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of September 30, 2021, we had accumulated losses of approximately \$130 million. We may continue to incur operating losses as we expand our ClearPoint system platform and our business generally.

Factors Which May Influence Future Results of Operations

The following is a description of factors that may influence our future results of operations, and that we believe are important to an understanding of our business and results of operations.

COVID-19

In March 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and the President of the United States later proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Extraordinary actions were taken by federal, state and local

governmental authorities to combat the spread of COVID-19, including issuances of “stay-at-home” directives and similar mandates that substantially restricted daily activities and for many businesses curtailed or ceased normal operations. These measures led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using the Company’s ClearPoint system. Although economic activity is returning to a normalized level, the Delta variant of COVID-19 continues to spread in the United States and across the globe. The ultimate impact of the Delta variant, and other new strains that may develop, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Delta and other variants and the response by governmental bodies and regulators, which could include vaccine mandates.

Furthermore, global supply chain disruptions, labor shortages, which may affect our ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic could have a material adverse effect on the Company’s business. The rapid development and fluidity of the situation preclude any prediction as to the ultimate impact COVID-19 will have on the Company’s business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States and globally.

Key Performance Indicators

The key performance indicators we utilize on a tactical basis are integrated into our longer-term strategic plan within the following categories:

- Functional neurosurgery navigation
 - Case volume – Underlying the revenue from sales of our functional neurosurgery navigation products reflected in the accompanying Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report are the procedures, or cases, performed in hospitals or at customer-sponsored contract research organizations utilizing one or more of our products or our clinical services. Case volume data is not influenced by variations in pricing or quantities of product used on a per case basis, and thus provide a more reliable indicator of the growth of our functional neurosurgery navigation line of business. Management analyzes case volume by hospital and by type of procedure to gain information that informs targeted sales and marketing activities. During the three and nine months ended September 30, 2021, the ClearPoint system was used in 227 and 690 cases, respectively, as compared to 200 and 507 cases during the same respective periods in 2020, representing increases of 14% for the comparative three-month periods and 36% for the comparative nine-month periods. Consistent with the discussion in the section “Results of Operations – Revenues,” we attribute these increases primarily to the reduced levels of elective neurosurgical procedures resulting from the initial onset and progression of the COVID-19 pandemic during the three-month and nine-month periods in 2020.
 - Number of “Active Surgery Centers” – For purposes of analyzing this performance indicator, an Active Surgery Center is a hospital or customer-sponsored contract research organization that has purchased products from us or has performed procedures utilizing our ClearPoint system within a rolling 24-month period, and includes hospital sites having purchased the ClearPoint system, as well as sites in which the ClearPoint system is being used on an evaluation basis. The justification for including “evaluation sites” is that our disposable neurosurgery product is sold to such hospitals for their use in cases. In addition to signifying growth, the number of Active Surgery Centers, when analyzed in conjunction with case volume data, further informs targeted sales and marketing activities and confirms where these activities have led to increased penetration of our product lines. As of September 30, 2021, the ClearPoint system was used in approximately 60 Active Surgery Centers, which is comparable to the number of such centers as of the same date in 2020.
- Biologics and drug delivery
 - Number of “Partners” – Underlying the revenue from sales of products and services to our biologics and drug delivery customers is the number of customers, or “Partners.” Our Partners consist of pharmaceutical and biotech companies, academic institutions, or customer-sponsored contract research organizations that are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to bypass the blood-brain barrier for the treatment of a variety of disorders. This is a novel area in which commercialization must be preceded by FDA-mandated clinical trials, which are expensive and time consuming to conduct, and for which the commercial success is uncertain, pending, in part, the outcome of those trials. While our revenue from sales of products and services to these Partners in support of their clinical trials is indicative of growth, the number of such relationships is also of importance as we recognize the possibility that some Partners’ research will reach commercial success, and others may not. To the extent our Partners achieve commercial success, our expectation is that we will share in such success through our Partners’ use of our products and services in their delivery of therapies. At September 30, 2021, we had commercial relationships with approximately 40 Partners, as compared with approximately 25 Partners as of the same date in 2020.
- Therapy products – We do not expect meaningful revenue from therapy products in 2021 insofar as we are targeting a limited market release of such products in 2022. As a result, our milestones in the therapy space are focused on refining the product and obtaining regulatory clearance. Should we be successful in achieving these milestones, we believe our initial performance indicators will focus on case volume and number of Active Surgery Centers, as are currently used in measuring our performance in functional neurosurgery navigation.
- Global scale and efficiency – We have been cautious in setting our goals for operations beyond the U.S. so as to conserve our resources and not establish a foreign presence in advance of being assured of a corresponding revenue stream. In late 2020 we took the first steps in leveraging the CE Marks we have for our ClearPoint system and SmartFlow cannula by establishing an initial presence in Europe for product sales and clinical advisory services. From this initial presence, we believe that future global key performance indicators will be similar to those described above for our U.S. business: case volume, number of Active Surgery Centers and number of biologics and drug delivery Partners.

Revenue

In 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the U.S. for general neurosurgery procedures; in February 2011 and May 2018, we also obtained CE marketing approval for our ClearPoint system and SmartFlow cannula, respectively; and in June 2020 we obtained CE marking approval for version 2.0 of our ClearPoint software and our Inflexion head fixation frame. Future revenue from sales of our ClearPoint platform products and services is difficult to predict and may not be sufficient to offset our continuing research and development expenses and our increasing selling, general and administrative expenses.

Generating recurring revenue from the sale of products is an important part of our business model for our ClearPoint system. Our product revenue was approximately \$3.3 million and \$8.9 million for the three and nine months ended September 30, 2021, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately \$1.2 million and \$3.2 million for the three and nine months ended September 30, 2021, respectively.

Our revenue recognition policies are more fully described in Note 2 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 in this Quarterly Report.

Cost of Revenue

Cost of revenue includes the direct costs associated with the assembly and purchase of components for functional neurosurgery navigation products, biologics and drug delivery products, non-neurosurgery therapy products, and ClearPoint capital equipment and software which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy. Cost of revenue also includes the allocation of manufacturing overhead costs and depreciation of loaned systems installed under our ClearPoint placement program, as well as provisions for obsolete, impaired, or excess inventory.

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products and enhancements. Such costs include salaries, travel, and benefits for research and development personnel; materials and laboratory supplies in research and development activities; consultant costs; and licensing costs related to technology not yet commercialized. We anticipate that, over time, our research and development costs may increase as we: (i) continue to develop enhancements to our ClearPoint system and software; and (ii) seek to expand the application of our technological platforms. From our inception through September 30, 2021, we have incurred approximately \$66 million in research and development expenses.

Product development timelines, likelihood of success, and total costs can vary widely by product candidate. There are also risks inherent in the regulatory clearance and approval process. At this time, we are unable to estimate with any certainty the costs that we will incur in our efforts to expand the application of our technological platforms.

Sales and Marketing, and General and Administrative Expenses

Our sales and marketing, and general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including related share-based compensation; marketing costs; professional fees, including fees for outside attorneys and accountants; occupancy costs; insurance; and other general and administrative expenses, which include, but are not limited to, corporate licenses, director fees, hiring costs, taxes, postage, office supplies and meeting costs. Our sales and marketing expenses are expected to increase due to costs associated with the commercialization of our ClearPoint system and the increased headcount necessary to support growth in operations.

Critical Accounting Policies

There have been no significant changes in our critical accounting policies during the three or nine months ended September 30, 2021 as compared to the critical accounting policies described in our 2020 Form 10-K.

Results of Operations

Three Months Ended September 30, 2021 Compared to the Three Months Ended September 30, 2020

| (Dollars in thousands) | Three Months Ended September 30, | | |
|-------------------------------------|----------------------------------|------------|-------------------|
| | 2021 | 2020 | Percentage Change |
| Product revenue | \$ 3,338 | \$ 2,371 | 41% |
| Service and other revenue | 1,236 | 1,148 | 8% |
| Total revenue | 4,574 | 3,519 | 30% |
| Cost of revenue | 1,486 | 903 | 65% |
| Gross profit | 3,088 | 2,616 | 18% |
| Research and development costs | 2,630 | 1,143 | 130% |
| Sales and marketing expenses | 1,826 | 1,493 | 22% |
| General and administrative expenses | 2,436 | 1,252 | 95% |
| Other expense: | | | |
| Other income (expense), net | 62 | (11) | NM% |
| Interest expense, net | (238) | (201) | 18% |
| Net loss | \$ (3,980) | \$ (1,484) | 168% |

NM – The percentage change is not meaningful.

Revenue. Total revenue was \$4.6 million for the three months ended September 30, 2021, and \$3.5 million for the three months ended September 30, 2020, which represents an increase of \$1.1 million, or 30%.

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 17% to \$2.2 million for the three months ended September 30, 2021, from \$1.8 million for the same period in 2020. This increase reflects the increase in functional neurosurgery navigation and therapy service revenue and the resumption in the three months ended September 30, 2021, of elective surgical procedures, which were postponed or cancelled during the three months ended September 30, 2020, due to the effects of the COVID-19 pandemic and the contribution of service revenue during the quarter ended September 30, 2021. Although elective surgeries have resumed, we are unable to determine the extent to which such factors as the timing, adoption or viability of such resumption will impact our revenue due to the persistence of the COVID-19 pandemic and our inability to determine the length of time that the COVID-19 pandemic will adversely affect our product revenue. There were no increases in functional neurosurgery product prices during the period between the three months ended September 30, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 39% to \$2.1 million for the three months ended September 30, 2021, from \$1.5 million for the same period in 2020. This increase was due to an increase, during the quarter ended September 30, 2021, relative to the same period in 2020, in biologic and drug delivery product revenue of \$0.7 million as we increased the number of biologic and drug delivery partners and as pre-clinical research and clinical trial investments by our biologics and drug delivery customers resume. This increase notwithstanding, our biologic and drug delivery customers are reestablishing their estimated timelines for initiation or resumption of their clinical trials, however, these timelines have not been finalized, given the uncertainties of when hospitals will be able to resume such clinical trial cases. Accordingly, depending on the length of the COVID-19 pandemic, future biologics and drug delivery revenue could be adversely impacted. There were no increases in biologics and drug delivery product prices during the period between the three months ended September 30, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 78% to \$0.4 million for the three months ended September 30, 2021, from \$0.2 million for the same period in 2020. Revenue from this product line historically has varied from quarter to quarter, and overall, we believe that hospitals' capital equipment acquisition activities remain at a low level, relative to the acquisition activity prior to the onset in 2020 of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the three months ended September 30, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Cost of Revenue and Gross Profit. Cost of revenue was \$1.5 million, resulting in gross profit of \$3.1 million and gross margin of 68%, for the three months ended September 30, 2021, and was \$0.9 million, resulting in gross profit of \$2.6 million and representing a gross margin of 74%, for the three months ended September 30, 2020. This decrease in gross margin was due primarily to: (a) \$0.1 million in additional excess & obsolete inventory reserve, (b) a decreased contribution, during the three months ended September 30, 2021 as compared to the same period in 2020, from service revenue, which carries a higher gross margin relative to our product lines, and (c) an increase in overhead costs allocated to cost of sales during the three months ended September 30, 2021 as compared to the same period in 2020.

Research and Development Costs. Research and development costs were \$2.6 million for the three months ended September 30, 2021, compared to \$1.1 million for the same period in 2020, an increase of \$1.5 million, or 130%. The increase was due primarily to increases in personnel costs of \$0.5 million due to growth in headcount, and product and software development of \$1.0 million, both resulting from our efforts to expand the applications of our technological platforms.

Sales and Marketing Expenses. Sales and marketing expenses were \$1.8 million for the three months ended September 30, 2021, compared to \$1.5 million for the same period in 2020, an increase of \$0.3 million, or 22%. This increase was due primarily to increases in personnel costs resulting from increases in headcount, travel expenses, and marketing activities, each such increase amounting to \$0.1 million.

General and Administrative Expenses. General and administrative expenses were \$2.4 million for the three months ended September 30, 2021, compared to \$1.3 million for the same period in 2020, an increase of \$1.2 million, or 95%. This increase was due primarily to increases in personnel costs of \$0.3 million, share-based compensation of \$0.3 million, and \$0.5 million attributed to rent, insurance costs, the allowance for doubtful accounts, IT expenses, and professional and consulting fees, each representing an increase of approximately \$0.1 million.

Interest Expense. Net interest expense for each of the three months ended September 30, 2021 and 2020 was \$0.2 million, due primarily to an increase in interest expense arising from issuance in December 2020 of the Second Closing Note, which was partially offset by a decrease in interest expense due to the conversion of one of the First Closing Notes. Additional information with respect to the First and Second Closing Notes is in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Nine Months Ended September 30, 2021 Compared to the Nine Months Ended September 30, 2020

| <i>(Dollars in thousands)</i> | Nine Months Ended September 30, | | |
|-------------------------------------|--|-------------------|--------------------------|
| | 2021 | 2020 | Percentage Change |
| Product revenue | \$ 8,863 | \$ 6,186 | 43% |
| Service and other revenue | 3,154 | 2,927 | 8% |
| Total revenue | <u>12,017</u> | <u>9,113</u> | 32% |
| Cost of revenue | 4,015 | 2,636 | 52% |
| Gross profit | 8,002 | 6,477 | 24% |
| Research and development costs | 6,251 | 2,774 | 125% |
| Sales and marketing expenses | 5,081 | 3,916 | 30% |
| General and administrative expenses | 6,062 | 3,742 | 62% |
| Other expense: | | | |
| Other expense, net | (60) | (5) | NM% |
| Interest expense, net | (809) | (1,240) | (35)% |
| Net loss | <u>\$ (10,261)</u> | <u>\$ (5,200)</u> | 97% |

NM – The percentage change is not meaningful.

Revenue. Total revenue was \$12.0 million for the nine months ended September 30, 2021, and \$9.1 million for the nine months ended September 30, 2020, which represents an increase of \$2.9 million, or 32%.

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 28% to \$5.9 million for the nine months ended September 30, 2021, from \$4.7 million for the same period in 2020. This increase reflects the resumption in the nine months ended September 30, 2021, of elective surgical procedures, which were postponed or cancelled during the nine months ended September 30, 2020, due to the effects of the COVID-19 pandemic. Although elective surgeries have resumed, we are unable to determine the extent to which such factors as the timing, adoption or viability of such resumption will impact our revenue due to the persistence of the COVID-19 pandemic and our inability to determine the length of time that the COVID-19 pandemic will adversely affect our product revenue. There were no increases in functional neurosurgery product prices during the period between the nine months ended September 30, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 39% to \$5.1 million for the nine months ended September 30, 2021, from \$3.7 million for the same period in 2020. This increase was due to an increase, during the nine months ended September 30, 2021, relative to the same period in 2020, in biologic and drug delivery product revenue of \$1.5 million as customer-sponsored pre-clinical research and customer-sponsored clinical trials resumed. This increase notwithstanding, our biologic and drug delivery customers are reestablishing their estimated timelines for initiation or resumption of their clinical trials, however, these timelines have not been finalized, given the uncertainties of when hospitals will be able to resume such clinical trial cases. Accordingly, depending on the length of the COVID-19 pandemic, future biologics and drug delivery revenue could be adversely impacted. There were no increases in biologics and drug delivery product prices during the period between the nine months ended September 30, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 24% to \$1.0 million for the nine months ended September 30, 2021, from \$0.8 million for the same period in 2020. Revenue from this product line historically has varied from quarter to quarter, and overall, we believe that hospitals' capital equipment acquisition activities remain at a low level, relative to the acquisition activity prior to the onset in 2020 of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the nine months ended September 30, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Cost of Revenue and Gross Profit. Cost of revenue was \$4.0 million, resulting in gross profit of \$8.0 million and gross margin of 67%, for the nine months ended September 30, 2021, and was \$2.6 million, resulting in gross profit of \$6.5 million and representing a gross margin of 71%, for the nine months ended September 30, 2020. This decrease in gross margin was due primarily to an increase in overhead costs allocated to cost of sales during the nine months ended September 30, 2021 as compared to the same period in

2020, which reflects the higher activity level in the 2021 period, relative to the same period in 2020. This was partially offset by an increased contribution of disposable products and service revenues during the nine months ended September 30, 2021 as compared to the same period in 2020, which carry a higher gross margin relative to other revenue lines, and a reduced contribution during the same comparative periods in sales of capital equipment, which carry a lower gross margin relative to other product lines.

Research and Development Costs. Research and development costs were \$6.3 million for the nine months ended September 30, 2021, compared to \$2.8 million for the same period in 2020, an increase of \$3.5 million, or 125%. The increase was due primarily to increases in personnel costs of \$1.6 million due to growth in headcount, and product and software development of \$1.8 million, both increases resulting from our efforts to expand the applications of our technological platforms.

Sales and Marketing Expenses. Sales and marketing expenses were \$5.1 million for the nine months ended September 30, 2021, compared to \$3.9 million for the same period in 2020, an increase of \$1.2 million, or 30%. This increase was due primarily to increases in personnel costs of \$0.6 million resulting from increases in headcount in our clinical and marketing teams, travel expenses of \$0.2 million due to increased activity, and marketing activities of \$0.2 million.

General and Administrative Expenses. General and administrative expenses were \$6.1 million for the nine months ended September 30, 2021, compared to \$3.7 million for the same period in 2020, an increase of \$2.3 million, or 62%. This increase was due primarily to increases in state franchise taxes of \$0.3 million, personnel costs of \$0.3 million, share-based compensation of \$0.4 million, occupancy costs of \$0.3 million, insurance costs of \$0.2 million, the allowance for doubtful accounts of \$0.2 million, and professional fees of \$0.2 million.

Interest Expense. Net interest expense for the nine months ended September 30, 2021 was \$0.8 million, compared to \$1.2 million for the same period in 2020. The decrease in interest expense is primarily due to the repayment of the 2010 Secured Notes in the first quarter of 2020 and the conversion of one of the First Closing Notes in the second quarter of 2021. The reduction in interest expense was partially offset by the additional interest expense arising from the issuance in December 2020 of the Second Closing Note. Additional information with respect to the First and Second Closing Notes is in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Liquidity and Capital Resources

We have incurred net losses since our inception which has resulted in a cumulative deficit at September 30, 2021 of approximately \$130 million. In addition, our use of cash from operations amounted to \$9.1 million for the nine months ended September 30, 2021 and \$7.8 million for the year ended December 31, 2020. Since inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable, product and service contracts and license arrangements.

In January 2020, we entered into the SPA with the 2020 Convertible Noteholders under which we issued the First Closing Notes having an aggregate principal amount of \$17.5 million, resulting in proceeds, net of financing costs and a commitment fee paid to one of the 2020 Convertible Noteholders, of approximately \$16.8 million. From the net proceeds received from the issuance of the First Closing Notes, which have a five-year term, we repaid and retired the 2010 Secured Notes that otherwise would have matured in October and November 2020.

The SPA also gave us the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase an additional \$5.0 million in principal amount of the Second Closing Note. On December 29, 2020, under the terms of the Amendment to the SPA which, among other provisions, increased the principal amount of the Second Closing Note, we issued the Second Closing Note to the 2020 Convertible Noteholder in the principal amount of \$7.5 million.

See Note 5 for additional information with respect to the 2020 Secured Notes.

In April 2020, we received \$0.9 million in proceeds under the terms of the PPP Loan. In November 2020, we were notified by the U.S. Small Business Administration that the loan had been forgiven under the provisions of the CARES Act.

As discussed in Note 7, on February 23, 2021, we completed a public offering of 2,127,660 shares of our common stock. Net proceeds from the offering were approximately \$46.8 million after deducting the underwriting discounts and commissions and other estimated offering expenses payable by us.

Based on the foregoing, in management's opinion, cash and cash equivalent balances at September 30, 2021, are sufficient to support our operations and meet our obligations for at least the next twelve months.

Cash Flows

Cash activity for the nine months ended September 30, 2021 and 2020 is summarized as follows:

| <i>(in thousands)</i> | Nine Months Ended September 30, | |
|---|------------------------------------|------------|
| | 2021 | 2020 |
| Cash used in operating activities | \$ (9,145) | \$ (5,406) |
| Cash used in investing activities | (130) | (441) |
| Cash provided by financing activities | 46,827 | 14,816 |
| Net change in cash and cash equivalents | \$ 37,552 | \$ 8,969 |

Net Cash Flows from Operating Activities. We used \$9.1 million and \$5.4 million of cash for operating activities during the nine months ended September 30, 2021 and 2020, respectively.

During the nine months ended September 30, 2021, uses of cash in operating activities primarily consisted of: (i) our \$10.3 million net loss; (ii) increases in accounts receivable of \$0.8 million, inventory of \$0.7 million, and prepaid expenses and other current assets of \$0.6 million; and (iii) decreases in lease liabilities of \$0.3 million. These uses were partially offset by: (a) an increase in accounts payable and accrued expenses of \$1.4 million; and (b) net non-cash expenses included in our net loss aggregating \$2.2 million and consisting primarily of changes in the allowance for doubtful accounts, depreciation and amortization, share-based compensation, payment-in-kind interest and amortization of debt issuance costs, original issue discounts on debt and lease rights-of-use, net of accretion in lease liabilities.

During the nine months ended September 30, 2020, uses of cash in operating activities primarily consisted of: (i) our \$5.2 million net loss; (ii) increases in accounts receivable of \$0.4 million, inventory of \$0.3 million, and prepaid expenses and other current assets of \$0.1 million; and (iii) decreases in accrued interest of \$1.0 million, lease liabilities of \$0.07 million, and deferred revenue of \$0.3 million. These uses were partially offset by: (a) a decrease in other assets of \$0.06 million; (b) an increase in accounts payable and accrued expenses of \$0.06 million; and (c) net non-cash expenses included in our net loss aggregating \$1.9 million and consisting primarily of depreciation and amortization, share-based compensation, and amortization of debt issuance costs, original issue discounts on debt and lease rights-of-use, net of accretion in lease liabilities.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the nine months ended September 30, 2021 were \$0.1 million and consisted of equipment acquisitions.

Net Cash Flows from Financing Activities. Net cash flows from financing activities for the nine months ended September 30, 2021, consisted of: (a) the proceeds, net offering costs, of \$46.8 million received from the public offering of our common stock; and (b) proceeds from the exercise of common stock options and warrants aggregating \$0.6 million, which were partially offset by tax payments of \$0.5 million related to shares withheld in connection with vesting of restricted stock awards.

Net cash flows from financing activities for the nine months ended September 30, 2020 consisted of the proceeds, net financing costs and discount paid as of that date, of \$16.8 million received from the issuance of the 2020 Secured Notes, and the proceeds of \$0.9 million from the PPP Loan. The proceeds from these activities were partially offset by the repayment of the 2010 Secured Notes amounting to \$2.8 million. The 2020 Secured Notes, the PPP Loan and the repayment of the 2010 Secured Notes are described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our ClearPoint system products and pursue additional applications for our technology platforms. Our cash balances are primarily held in a variety of demand accounts with a view to liquidity and capital preservation.

Because of the numerous risks and uncertainties associated with the development and commercialization of medical devices, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to successfully commercialize our ClearPoint system products and pursue additional applications for our technology platforms. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the ultimate duration and impact of the COVID-19 pandemic;
- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the cost of pursuing additional applications of our technology platforms under current collaborative arrangements, and the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Off-Balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

Our exposure to market risk is limited primarily to interest income and expense sensitivity, which is affected by changes in the general level of U.S. interest rates.

Our investments are in short-term bank deposits and institutional money market funds. The primary objective of our investment activities is to preserve principal while at the same time maximizing income we receive without significantly increasing risk. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure.

At September 30, 2021, we had \$10.0 million of principal outstanding under the First Closing Note, which is subject to interest rate fluctuations. A one-percent increase in one-month LIBOR would result in no net increase in interest expense on an annualized basis due to the fact that the First Closing Note is subject to a LIBOR floor of 2.00% and one-month LIBOR was below the floor as of September 30, 2021. Information with respect to the First Closing Note may be found in Note 5 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Foreign Currency Risk

To date, we have not recorded a significant amount of sales in currencies other than U.S. dollars, and have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks, which at present, are not material. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2021 to ensure that the 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2021.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2021, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 1A. RISK FACTORS.

There have been no material changes to the risk factors disclosed in our 2020 Form 10-K.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

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ITEM 6. EXHIBITS.

The exhibits listed below are filed, furnished, or incorporated by reference as part of this Quarterly Report.

| Exhibit Number | Exhibit Description |
|-----------------------|--|
| 31.1* | Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934 |
| 31.2* | Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934 |
| 32+ | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code |
| 101.INS* | XBRL Instance |
| 101.SCH* | XBRL Taxonomy Extension Schema |
| 101.CAL* | XBRL Taxonomy Extension Calculation |
| 101.DEF* | XBRL Taxonomy Extension Definition |
| 101.LAB* | XBRL Taxonomy Extension Labels |
| 101.PRE* | XBRL Taxonomy Extension Presentation |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed herewith.

+ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and it is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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SIGNATURES

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

Date: November 9, 2021

CLEARPOINT NEURO, INC.

By: /s/ Joseph M. Burnett
Joseph M. Burnett

*Chief Executive Officer
(Principal Executive Officer)*

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
*Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

I, Joseph M. Burnett, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2021, of ClearPoint Neuro, 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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2021

/s/ Joseph M. Burnett

Joseph M. Burnett
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

I, Danilo D'Alessandro, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2021, of ClearPoint Neuro, 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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2021

/s/ Danilo D'Alessandro
Danilo D'Alessandro
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) UNDER
THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE**

Each of the undersigned, Joseph M. Burnett and Danilo D'Alessandro, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended June 30, 2021, of ClearPoint Neuro, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2021

/s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer

/s/ Danilo D'Alessandro
Danilo D'Alessandro
Chief Financial Officer