

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, 2022**

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_ to \_\_\_\_

Commission file number: **001-34822**

**ClearPoint Neuro, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction  
of Incorporation or Organization)

**58-2394628**

(IRS Employer  
Identification Number)

**120 S. Sierra Ave., Suite 100  
Solana Beach, California**

(Address of Principal Executive Offices)

**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   
Non-accelerated filer

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 3, 2022, there were 24,554,557 shares of common stock outstanding.

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CLEARPOINT NEURO, INC.

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**Trademarks, Trade Names and Service Marks**

*ClearPoint Neuro*<sup>®</sup>, *ClearPoint*<sup>®</sup>, *ClearTrace*<sup>®</sup>, *SmartFlow*<sup>®</sup>, *SmartFrame*<sup>®</sup>, *SmartGrid*<sup>®</sup>, *Inflexion*<sup>™</sup>, *SmartTwist*<sup>™</sup>, *SmartTip*<sup>™</sup>, *ClearPoint Pursuit*<sup>®</sup>, *ClearPoint Maestro*<sup>™</sup>, *ClearPoint Revolution*<sup>™</sup>, *SmartFrame Array*<sup>™</sup>, *ClearPoint Orchestra*<sup>™</sup>, *ClearPoint Prism*<sup>™</sup>, *When Your Path is Unclear, We Point The Way*<sup>™</sup>, and *MRI Interventions*<sup>®</sup> 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.

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## 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,” and relate to expectations for revenues and costs, and the adequacy of the Company’s cash and cash equivalent balances and short-term investments to support the Company’s operations and meet its obligations for at least the next twelve months.

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.

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.

In evaluating forward-looking statements, you should refer to (i) the section titled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which we filed with the United States Securities and Exchange Commission (“SEC”) on March 9, 2022 (the “2021 Form 10-K”), (ii) Item 2 of this Quarterly Report, under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations -- Factors Which May Influence Future Results of Operations” and (iii) Part II, Item 1.A of this Quarterly Report. Due to the nature of these risk 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.

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## 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, 2022 (Unaudited)	December 31, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,712	\$ 54,109
Short-term investments	21,749	—
Accounts receivable, net	3,411	2,337
Inventory, net	8,284	4,938
Prepaid expenses and other current assets	1,658	508
Total current assets	53,814	61,892
Property and equipment, net	629	539
Operating lease rights of use	1,866	2,241
Software license inventory	485	519
Licensing rights	850	265
Other assets	94	125
Total assets	<u>\$ 57,738</u>	<u>\$ 65,581</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,387	\$ 427
Accrued compensation	2,187	2,604
Other accrued liabilities	1,249	537
Operating lease liabilities, current portion	537	507
Deferred product and service revenue, current portion	735	678
Total current liabilities	6,095	4,753
Operating lease liabilities, net of current portion	1,535	1,939
Deferred product and service revenue, net of current portion	351	264
2020 senior secured convertible note payable, net	9,879	9,838
Total liabilities	17,860	16,794
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 24,500,832 shares issued and outstanding at September 30, 2022; and 23,665,991 issued and outstanding at December 31, 2021	245	237
Additional paid-in capital	185,615	182,482
Accumulated deficit	(145,982)	(133,932)
Total stockholders' equity	39,878	48,787
Total liabilities and stockholders' equity	<u>\$ 57,738</u>	<u>\$ 65,581</u>

See accompanying notes to Condensed Consolidated Financial Statements.

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

	<b>For The Three Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Product revenue	\$ 3,130	\$ 3,338
Service and other revenue	2,016	1,236
Total revenue	5,146	4,574
Cost of revenue	1,434	1,533
Gross profit	3,712	3,041
Research and development costs	2,453	2,601
Sales and marketing expenses	2,139	1,808
General and administrative expenses	2,915	2,436
Operating loss	(3,795)	(3,804)
Other expense:		
Other (expense) income, net	(25)	62
Interest income (expense), net	32	(238)
Net loss	\$ (3,788)	\$ (3,980)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.15)	\$ (0.18)
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,497,636	22,522,460

	<b>For The Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Product revenue	\$ 9,750	\$ 8,863
Service and other revenue	5,627	3,154
Total revenue	15,377	12,017
Cost of revenue	5,162	4,078
Gross profit	10,215	7,939
Research and development costs	7,270	6,208
Sales and marketing expenses	6,171	5,061
General and administrative expenses	8,637	6,062
Operating loss	(11,863)	(9,392)
Other expense:		
Other expense, net	(22)	(60)
Interest expense, net	(165)	(809)
Net loss	\$ (12,050)	\$ (10,261)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.50)	\$ (0.50)
Weighted average shares used in computing net loss per share:		
Basic and diluted	24,058,205	20,545,080

See accompanying notes to Condensed Consolidated Financial Statements.

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

**For The Nine Months Ended September 30, 2022**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2022	23,665,991	\$ 237	\$ 182,482	\$ (133,932)	\$ 48,787
Issuances of common stock:					
Share-based compensation	29,916	—	899	—	899
Warrant and option exercises (cash and cashless)	12,211	—	3	—	3
Net loss for the period	—	—	—	(3,959)	(3,959)
Balances, March 31, 2022	23,708,118	\$ 237	\$ 183,384	\$ (137,891)	\$ 45,730
Issuances of common stock:					
Share-based compensation	379,122	4	876	—	880
Warrant exercises (cash and cashless)	367,006	4	249	—	253
Issuance of common stock under employee stock purchase plan	26,354	—	260	—	260
Net loss for the period	—	—	—	(4,303)	(4,303)
Balances, June 30, 2022	24,480,600	\$ 245	\$ 184,769	\$ (142,194)	\$ 42,820
Issuances of common stock:					
Share-based compensation	20,738	—	1,175	—	1,175
Option exercises (cash and cashless)	23,763	—	7	—	7
Payments for taxes related to net share settlement of equity awards	(24,269)	—	(336)	—	(336)
Net loss for the period	—	—	—	(3,788)	(3,788)
Balances, September 30, 2022	24,500,832	\$ 245	\$ 185,615	\$ (145,982)	\$ 39,878



**For The Nine Months Ended September 30, 2021**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, 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)
Balances, 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)
Balances, 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)
Balances, September 30, 2021	22,855,187	\$ 229	\$ 173,674	\$ (129,783)	\$ 44,120

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (12,050)	\$ (10,261)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	(92)	170
Depreciation and amortization	224	113
Share-based compensation	2,954	1,153
Payment-in-kind interest	—	285
Amortization of debt issuance costs and original issue discounts	41	73
Amortization of lease rights of use, net of accretion in lease liabilities	400	400
Accretion of discounts on short-term investments	(159)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(982)	(848)
Inventory, net	(3,318)	(682)
Prepaid expenses and other current assets	(1,150)	(599)
Other assets	31	(28)
Accounts payable and accrued expenses	1,255	1,418
Lease liabilities	(400)	(312)
Deferred revenue	144	(27)
Net cash flows from operating activities	<u>(13,102)</u>	<u>(9,145)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(214)	(130)
Acquisition of licensing rights	(678)	—
Purchase of short-term investments	(21,590)	—
Net cash flows from investing activities	<u>(22,482)</u>	<u>(130)</u>
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	—	46,785
Proceeds from stock option and warrant exercises	263	584
Proceeds from issuance of common stock under employee stock purchase plan	260	—
Payments for taxes related to net share settlement of equity awards	(336)	(542)
Net cash flows from financing activities	<u>187</u>	<u>46,827</u>
Net change in cash and cash equivalents	<u>(35,397)</u>	<u>37,552</u>
Cash and cash equivalents, beginning of period	54,109	20,099
Cash and cash equivalents, end of period	<u>\$ 18,712</u>	<u>\$ 57,651</u>

**SUPPLEMENTAL CASH FLOW INFORMATION**

Cash paid for:		
Income taxes	\$ —	\$ —
Interest	\$ 351	\$ 495

#### NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- The Company had less than \$0.1 million in capital expenditures accrued but not yet paid at September 30, 2022.
- During the nine months ended September 30, 2022 and 2021, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of less than \$0.1 million, between loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets, and inventory.
- 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 (as defined in Note 1) and a corresponding reduction of additional paid-in capital, each in the amount of \$3.1 million.
- As discussed in Note 6, 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 approximately 1,256,143 million shares of the Company's common stock, at a \$6.00 per share price. 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 commercial-stage medical device company focused on the development and commercialization of innovative platforms for performing minimally invasive surgical procedures in the brain. From the Company’s inception in 1998, the Company deployed significant resources to fund its efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies it develops. In 2021, the Company’s efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room setting, as well as consulting services for pharmaceutical and biotech companies, academic institutions, and contract research organizations.

The Company’s initial product offering, the ClearPoint system, is an integrated system comprised of capital equipment and disposable products, designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The ClearPoint Array Neuro Navigation System and its principal disposable component, introduced in 2021, is designed to be deployed in an operating room setting while also being usable in an MRI suite. Both systems provide guidance for the placement and operation of instruments or devices during the planning and operation of neurosurgical procedures. 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 neurosurgical interventional procedures; in February 2011, the Company also obtained CE marking for its ClearPoint system. In 2011 and 2018, the Company received 510(k) clearance and CE marking, respectively, for its SmartFlow cannula which is being used, or is under evaluation, by approximately 50 pharmaceutical and biotech companies, academic institutions, or contract research organizations having a focus on biologics and drug delivery. In September 2022 the ClearPoint Prism™ Neuro Laser Therapy System, for which ClearPoint Neuro has exclusive global commercialization rights, received 510(k) clearance through the Company’s Swedish partner Clinical Laserthermia Systems (CLS). The Prism laser represents the first therapy product the Company will commercialize.

*Macroeconomic Trends*

We continue to monitor the impact of various macroeconomic trends, such as global economic and supply chain disruptions, geopolitical instability, labor shortages and inflationary conditions, and the continuing impacts of the COVID-19 pandemic. Changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause changes in fiscal and monetary policy. Impacts from inflationary pressures, such as an increasing costs for research and development of our products, administrative and other costs of doing business, and our availability to access capital markets and other sources of funding in the future could adversely affect our business, financial condition and results of operations. Additionally, these trends could adversely affect our customers, which could impact their willingness to spend on our products and services. The rapid development and fluidity of these situations precludes any prediction as to the ultimate impact they will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments.

*Liquidity*

The Company has incurred net losses since its inception, which has resulted in a cumulative deficit at September 30, 2022 of \$46.0 million. In addition, the Company’s use of cash from operations amounted to \$13.1 million for the nine months ended September 30, 2022, and \$12.7 million for the year ended December 31, 2021. Since its inception, the Company has financed its operations principally from the sale of equity securities and the issuance of notes payable.

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.

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

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 Notes, 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, the Company issued the Second Closing Note in the principal amount of \$7.5 million to one of the 2020 Convertible Noteholders.

See Note 6 for additional information with respect to the 2020 Secured Notes.

As discussed in Note 8, 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.

**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, 2021 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 2021 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2021 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, 2022 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 and related disposables. 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 excess and obsolete items and provides a reserve upon identification of potentially excess or obsolete items.

*Intangible Assets*

The Company is a party to a license agreement which provides rights to the Company for the development and commercialization of products. Under the term of the license agreement, the Company made payments to the licensor upon execution of the license agreement for access to the underlying technology and future payments upon achievement of regulatory and commercialization milestones as defined in the license agreement. In Q3 2022, the Company made a payment to the licensor for the achievement of a regulatory milestone, which acts as a prepayment for future royalties.

In conformity with Accounting Standards Codification Section 350, “Intangibles – Goodwill and Other,” the Company amortizes its investment in the upfront license rights described above over an expected useful life of five years, or as commercial sales occur for the royalty prepayment. In addition, the Company periodically evaluates the recoverability

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

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.

*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 revenue 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 products (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), is generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and are generally recognized at the point in time of shipping to the customer, which is the point at which legal title, and risks and rewards of ownership, transfer to the customer. For certain customers, legal title and risks and rewards of ownership transfer upon delivery to the customer as stated in their respective contracts, in which case revenue is recognized upon delivery.
- *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 preceded by an evaluation period is recognized upon delivery to the customer and installation. For capital equipment that does not require installation, revenue is recognized upon shipment, however, for those customers where legal title and risks and rewards of ownership transfer upon delivery, revenue is recognized at such time.

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

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.
- *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 or hours of services provided to the customer 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 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.

The Company may also enter into contracts with customers who own ClearPoint capital equipment, which bundle maintenance and support services and access to software and hardware upgrades made commercially available over the term of the contract, for a single contract price, typically paid on an annual basis. The Company allocates the contract price among the performance obligations based on the relative stand-alone prices for each such performance obligation and recognizes the revenue ratably on a monthly basis. A time-elapsed output method is used as the Company is providing a stand-ready service for each of the performance obligations.

- *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 concurrent with the recognition of revenue of the related capital equipment.

The Company operates in one industry segment, and the predominance of 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.

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*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 8, and the potential conversion of the First Closing Note, as described in Note 6, 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.

*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 may at times invest its excess cash in interest bearing accounts and U.S. Treasury Bills. It classifies all highly liquid investments with original stated maturities of three months or less from the date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months but less than twelve months as short term investments. The Company classifies the U.S. Treasury Bills as held-to-maturity in accordance with ASC 320, "Investments - Debt and Equity Securities." Held-to-maturity securities are those securities which the Company has the ability and intent to hold until maturity and are recorded at amortized cost on the accompanying condensed consolidated balance sheet, adjusted for the accretion of discounts using the interest method.

The Company holds the remainder of its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At September 30, 2022, the Company had approximately \$9.9 million in bank balances that were in excess of the insured limits.

At September 30, 2022, there were two customers whose accounts receivable balances represented 16% and 15% of accounts receivable at that date. At December 31, 2021, one customer accounted for 15% of accounts receivable at that date.

One pharmaceutical customer, a related party who is a stockholder, a noteholder, and who has a representative on the Company's Board of Directors (see Note 6), for whom the Company provides hardware, software, clinical services and market development services in support of the customer's clinical trials, and from whom the Company earns a quarterly fee, accounted for 14% and 18% of total sales in the three-month periods ended September 30, 2022 and 2021, respectively, and 16% and 19% of total sales in the nine-month periods ended September 30, 2022 and 2021, 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, 2022 and December 31, 2021 was \$0.2 million and \$0.3 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



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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 6) 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 statement of operations for the three and nine months ended September 30, 2022 contains certain items formerly classified as sales and marketing expenses and research and development expenses that have been reclassified to cost of revenue. The accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2021 have been conformed to the 2022 presentation.

**3. Revenue Recognition**

*Revenue by Service Line*

<i>(in thousands)</i>	<b>Three Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
Functional neurosurgery navigation and therapy		
Disposable products	\$ 2,045	\$ 2,004
Services	375	150
Subtotal – Functional neurosurgery navigation and therapy	2,420	2,154
Biologics and drug delivery		
Disposable products	798	1,137
Services	1,448	920
Subtotal – Biologics and drug delivery revenue	2,246	2,057
Capital equipment and software		
Systems and software products	287	197
Services	193	166
Subtotal – Capital equipment and software revenue	480	363
<b>Total revenue</b>	<b>\$ 5,146</b>	<b>\$ 4,574</b>

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<i>(in thousands)</i>	Nine Months Ended September 30,	
	2022	2021
Functional neurosurgery navigation and therapy		
Disposable products	\$ 5,706	\$ 5,782
Services	1,125	150
Subtotal – Functional neurosurgery navigation and therapy	6,831	5,932
Biologics and drug delivery		
Disposable products	2,873	2,501
Services	3,935	2,605
Subtotal – Biologics and drug delivery revenue	6,808	5,106
Capital equipment and software		
Systems and software products	1,171	580
Services	567	399
Subtotal – Capital equipment and software revenue	1,738	979
<b>Total revenue</b>	<b>\$ 15,377</b>	<b>\$ 12,017</b>

*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 generally upon shipment of such products or delivery of such 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 Company may also enter into agreements with customers that bundle the capital equipment and software-related service fees with software and hardware upgrades that are made commercially available over the term of the contract. The unearned portion of all such fees is classified as deferred revenue.

During the three and nine months ended September 30, 2022, the Company recognized capital equipment and software-related service revenue of approximately \$0.1 million and \$0.4 million, respectively, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2021.

Revenue with respect to remaining performance obligations related to capital equipment and software-related service agreements and the upfront payments discussed under the heading "Contract Balances" above amounted to approximately \$0.8 million at September 30, 2022. The Company expects to recognize approximately 59% of this revenue over the next twelve months and the remainder thereafter.

**4. Fair Value Measurement**

Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The fair value of cash and cash equivalents of \$18.7 million and \$54.1 million as of September 30, 2022, and December 31, 2021, respectively, is derived using Level 1 inputs. The cash equivalents are comprised of short-term

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bank deposits, money market funds, and U.S. Treasury bills with original maturities of three months or less, and the carrying value is a reasonable estimate of fair value.

At September 30, 2022, the Company had \$21.7 million of short-term investments, consisting of six and twelve month U.S. Treasury Bills, which are classified as held to maturity and carried at amortized cost, adjusted for the accretion of discounts using the interest method. The carrying value of the debt securities approximates fair value based on Level 1 inputs. The Company has the intent and ability to hold these investments to maturity in order to collect interest payments over the life of the investments.

**5. Inventory**

Inventory consists of the following as of September 30, 2022 and 2021:

<i>(in thousands)</i>	September 30, 2022	December 31, 2021
Raw materials and work in process	\$ 5,950	\$ 2,718
Software licenses	210	210
Finished goods	2,124	2,010
Inventory, net, included in current assets	8,284	4,938
Software licenses – non-current	485	519
Total	<u>\$ 8,769</u>	<u>\$ 5,457</u>

**6. Note Payable**

As a result of the transactions described below, an aggregate principal amount of \$10 million of the First Closing Note was outstanding at September 30, 2022. At the option of the holder, who is a customer and has a representative on the Company's Board of Directors, at any time prior to maturity on January 29, 2025, the principal amount may be convertible to the Company's common stock at a conversion price of \$6.00, subject to adjustments as set forth in the SPA and the note agreement.

On January 29, 2020, the Company completed a financing transaction with two investors (the "2020 Convertible Noteholders"), whereby the Company issued an aggregate principal amount of \$17.5 million of First Closing Notes pursuant to the SPA, which, unless earlier converted or redeemed, mature on the fifth anniversary of the issuance 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 the 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

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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 7% 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 to one of the 2020 Convertible Noteholders.

On November 3, 2021, the holder of the Second Closing Note converted the entire \$7.5 million principal amount of such note, along with related accrued and payment in-kind interest aggregating \$0.3 million, into 773,446 shares of the Company's common stock.

The aggregate carrying amount of the outstanding First Closing Note in the accompanying September 30, 2022 and December 31, 2021 condensed consolidated balance sheets is presented net of financing costs, comprised of commissions and legal expenses, having an unamortized balance of \$0.1 million and \$0.2 million at those respective dates. Prior to the conversion of the First Closing Note held by the Converting Noteholder, the aggregate carrying amount was 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 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, were charged to interest expense over the respective terms of the First Closing Notes under the effective interest method.

Upon issuance of the Second Closing Note, the carrying amount was presented net of a discount, amounting to approximately \$0.1 million, which represented the value of the deemed beneficial conversion feature embedded in the Second Closing Note. A 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. As discussed in Note 2, effective January 1, 2021, the Company adopted the provisions of ASU 2020-06 which no longer required such beneficial conversion features to be separately accounted for, and as a result, the accompanying December 31, 2021 condensed consolidated balance sheet reflects the elimination of both the discount and a corresponding increase to additional paid-in capital.

Under the terms of the SPA, as amended, the Company had the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase the Third Closing Note, and the 2020 Convertible Noteholder had the right, but not the obligation, to purchase such note. As of January 11, 2022, the Company's right expired.

The outstanding First Closing Note is 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.

*Scheduled Note Payable Maturity*

Scheduled principal payment as of September 30, 2022 with respect to the remaining note payable is summarized as follows:

<b>Year ending December 31,</b>	<i>(in thousands)</i>
2025	\$ 10,000
Total scheduled principal payment	10,000
Less: Unamortized financing costs	(121)
Total	\$ 9,879

**7. Leases**

The Company leases space in Irvine, California, that houses office space and a manufacturing facility under a non-cancellable 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

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Solana Beach, California, that serves as its corporate headquarters and houses certain management and research and development personnel. 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 leases are classified as operating leases in conformity with GAAP.

The aggregate lease costs, included in general and administrative expense, were \$0.1 million for each of the three months ended September 30, 2022 and 2021, and was \$0.4 million for each of the nine months ended September 30, 2022 and 2021.

**8. 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.

*Share-Based Compensation Expense*

The Company records share-based compensation expense on a straight-line basis over the related vesting period and recognizes forfeitures as they occur. The following table sets forth share-based compensation expense included in general and administrative expense in the condensed consolidated statements of operations:

<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
<i>(in thousands)</i>		<i>(in thousands)</i>	
<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
\$1,175	\$586	\$2,954	\$1,153

As of September 30, 2022, there was \$1.6 million and \$6.0 million of total unrecognized compensation expense related to stock options and restricted stock, respectively, which is expected to be recognized over a weighted-average period of 2.0 years and 2.3 years, respectively.

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*Stock Option Activity*

Stock option activity under all of the Company's plans during the nine months ended September 30, 2022 is summarized below:

	Stock Options	Weighted-average Exercise price per share	Weighted-average Remaining Contractual Life (in years)	Intrinsic Value <sup>(1)</sup> (in thousands)
Outstanding at December 31, 2021	1,350,473	\$ 10.10		
Granted	147,723	\$ 10.91		
Exercised	(29,000)	\$ 2.36		
Forfeited or expired	(69,723)	\$ 43.24		
Outstanding at September 30, 2022	<u>1,399,473</u>	<u>\$ 8.70</u>	<u>6.4</u>	<u>\$ 7,251</u>

(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.

*Restricted Stock Activity*

Restricted stock activity, which includes restricted stock awards ("RSA") and restricted stock unit awards ("RSU"), for the nine months ended September 30, 2022 is summarized below:

	Restricted Stock	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2021	380,105	\$ 10.41
Granted	471,863	\$ 11.10
Vested	(169,666)	\$ 13.28
Forfeited	(26,941)	\$ 13.92
Outstanding at September 30, 2022	<u>655,361</u>	<u>\$ 11.27</u>

*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 were made available for issuance pursuant to the terms of the ESPP. Each offering period is for six months, and the first offering period commenced on July 1, 2021. During the six months ended June 30, 2022, 26,354 shares were purchased at an average per share price of \$9.86.

*Warrants*

Warrants to purchase shares of the Company's common stock were issued in connection with financing transactions in 2015 and 2017. 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, 2022 will terminate in 2023.

Common stock warrant activity for the nine months ended September 30, 2022 is as follows:

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	Warrant Shares	Weighted-average Exercise price per share	Intrinsic Value <sup>(1)</sup> <i>(in thousands)</i>
Outstanding at December 31, 2021	668,907	\$ 2.97	
Exercised	(462,353)	\$ 2.20	
Terminated	(170,000)	\$ 2.20	
Outstanding at September 30, 2022	36,554	\$ 16.23	\$ —

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

**9. Subsequent Event**

On November 4, 2022, the Company entered into a lease agreement (the "Lease Agreement") with the Hedda Marosi Living Trust and the Stella Feder Trust (collectively, the "Lessor") to lease an approximately 19,462 square foot industrial building located at 6349 Paseo Del Lago, Carlsbad, CA 92011 (the "Leased Premises"). The Company will use the Leased Premises as an office and manufacturing facility. The lease term commences on June 1, 2023 and ends on May 31, 2033 (the "Lease Term"). The base rent payable under the Lease Agreement is \$36,977.80 per month. The base rent is subject to annual increases of 3.5% during the Lease Term. In addition to the base rent, the Company is responsible for certain costs and charges, including insurance, operating, and tax expenses. The Company also has two options to extend the Lease Term for thirty-six months or sixty months, at the fair market rental value.

## 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 2021 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 commercial-stage medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain. We have deployed significant resources to fund our efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies developed by our company. Beginning in 2021, our efforts have expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room, as well as consulting services for pharmaceutical and biotech companies, academic institutions, and contract research organizations.

Since 2020, we have evolved to become a company comprised of two parts. The first foundational part is a medical device company providing medical devices for neurosurgery applications. The second part is focused on collaborating with pharmaceutical and biotech companies, academic institutions, and contract research organizations to develop delivery methodologies for neurological drugs. Currently, there are approximately 50 such entities who are either evaluating or using our SmartFlow cannula and, in certain cases, in conjunction with our full ClearPoint Neuro Navigation platform.

Substantially all our product revenue for the three and nine months ended September 30, 2022 and 2021 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 and the issuance of convertible and other secured notes. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of September 30, 2022, we had accumulated losses of \$146.0 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.

#### *Macroeconomic Trends*

We continue to monitor the impact of various macroeconomic trends, such as global economic and supply chain disruptions, geopolitical instability, labor shortages and inflationary conditions, and the continuing impacts of the COVID-19 pandemic. Changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause changes in fiscal and monetary policy. Impacts from inflationary pressures, such as increasing costs for research and development of our products, administrative and other costs of doing business, and our availability to access capital markets and other sources of funding in the future could adversely affect our business, financial condition and results of operations. Additionally, these trends could adversely affect our customers, which could impact their willingness to spend on our products and services. The rapid development and fluidity of these situations precludes any prediction as to the ultimate impact they will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments.

#### *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 marking for our ClearPoint system and SmartFlow



cannula, respectively; and in June 2020 we obtained CE marking for version 2.0 of our ClearPoint software and our Inflexion head fixation frame. In January 2021, we received 510(k) clearance for the SmartFrame Array Neuro Navigation System. In September 2022 the ClearPoint Prism™ Neuro Laser Therapy System, for which we have exclusive global right to commercialize, received 510(k) clearance through our Swedish partner Clinical Laserthermia Systems (“CLS”). The Prism laser represents the first therapy product we will commercialize. 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 \$3.1 million and \$9.8 million for the three and nine months ended September 30, 2022, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately \$2.0 million and \$5.6 million for the three and nine months ended September 30, 2022, respectively, of which 72% and 70%, respectively, related to the biologics and drug delivery service line.

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.

Underlying the revenue from sales of products and services to our biologics and drug delivery customers is the number of direct customers and end users of our products and/or services (“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 our biologics and drug delivery customers is indicative of growth, the number of Partner 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, 2022, we had approximately 50 Partners, as compared with approximately 40 Partners as of the same date in 2021.

#### ***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, as well as labor hours for the cost of providing consulting and service revenue. 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; outside 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 SmartFlow cannula; and (ii) seek to expand the application of our technological platforms. From our inception through September 30, 2022, we have incurred approximately \$77 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 share-based compensation; marketing costs; professional fees, including fees or 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, information technology and meeting costs. Our sales and marketing expenses are expected to increase due to costs associated with the continued commercialization of our ClearPoint system and the increased headcount necessary to support growth in operations.

### Critical Accounting Policies and Estimates

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2022, as compared to the critical accounting policies and estimates described in our 2021 Form 10-K.

### Results of Operations

#### Three Months Ended September 30, 2022, Compared to the Three Months Ended September 30, 2021

<i>(Dollars in thousands)</i>	Three Months Ended September 30,		
	2022	2021	Percentage Change
Product revenue	\$ 3,130	\$ 3,338	(6) %
Service and other revenue	2,016	1,236	63 %
Total revenue	5,146	4,574	13 %
Cost of revenue	1,434	1,533	(6) %
Gross profit	3,712	3,041	22 %
Research and development costs	2,453	2,601	(6) %
Sales and marketing expenses	2,139	1,808	18 %
General and administrative expenses	2,915	2,436	20 %
Other expense:			
Other (expense) income, net	(25)	62	NM%
Interest income (expense), net	32	(238)	(114) %
Net loss	\$ (3,788)	\$ (3,980)	(5) %

NM – The percentage change is not meaningful.

*Revenue.* Total revenue was \$5.1 million for the three months ended September 30, 2022, and \$4.6 million for the three months ended September 30, 2021, which represents an increase of \$0.6 million, or 13%.

<i>(Dollars in thousands)</i>	Three Months Ended September 30,		
	2022	2021	Percentage Change
Functional neurosurgery navigation and therapy			
Disposable products	\$ 2,045	\$ 2,004	2 %
Services	375	150	150 %
Subtotal – Functional neurosurgery navigation and therapy	2,420	2,154	12 %
Biologics and drug delivery			
Disposable products	798	1,137	(30) %
Services	1,448	920	57 %
Subtotal – Biologics and drug delivery revenue	2,246	2,057	9 %
Capital equipment and software			
Systems and software products	287	197	46 %
Services	193	166	16 %
Subtotal – Capital equipment and software revenue	480	363	32 %
Total revenue	\$ 5,146	\$ 4,574	13 %

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 12% to \$2.4 million for the three months ended September 30, 2022, from \$2.2 million for the same period in 2021. This increase reflects \$0.4 million of service revenue related to development services during the three months ended September 30, 2022, compared to \$0.2 million service revenue for the same period in 2021.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 9% to \$2.2 million for the three months ended September 30, 2022, from \$2.1 million for the same period in 2021. This increase is attributable to a \$0.5 million increase in service revenue related to new and continued partnerships with pharmaceutical and biotech companies, academic institutions, and contract research organizations during the three months ended September 30, 2022, compared to the same period in 2021, partially offset by a \$0.3 million decrease in product revenue.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 32% to \$0.5 million for the three months ended September 30, 2022, from \$0.4 million for the same period in 2021 due primarily to an increase in the placements of ClearPoint capital and software.

*Cost of Revenue and Gross Profit.* Cost of revenue was \$1.4 million, resulting in gross profit of \$3.7 million and gross margin of 72%, for the three months ended September 30, 2022, and was \$1.5 million, resulting in gross profit of \$3.0 million and representing a gross margin of 66%, for the three months ended September 30, 2021. The increase in gross margin was primarily due to an increased contribution from service revenue, which carries a higher gross margin relative to product revenue, during the three months ended September 30, 2022 as compared to the same period in 2021 and by lower overhead expenses. This was partially offset by an increase in excess and obsolete reserves.

*Research and Development Costs.* Research and development costs were \$2.5 million for the three months ended September 30, 2022, compared to \$2.6 million for the same period in 2021, a decrease of \$0.1 million, or 6%. The decrease was due primarily to lower product development costs as a result of reprioritization of certain research and development initiatives.

*Sales and Marketing Expenses.* Sales and marketing expenses were \$2.1 million for the three months ended September 30, 2022, compared to \$1.8 million for the same period in 2021, an increase of \$0.3 million, or 18%. This increase was due primarily to additional personnel costs resulting from increases in headcount of \$0.2 million, as well as increases in travel costs of \$0.1 million.

*General and Administrative Expenses.* General and administrative expenses were \$2.9 million for the three months ended September 30, 2022, compared to \$2.4 million for the same period in 2021, an increase of \$0.5 million, or 20%. This increase was due primarily to increased share-based compensation of \$0.5 million.

*Interest Expense.* Net interest income for the three months ended September 30, 2022 was \$0.03 million, compared to \$0.2 million net interest expense for the same period in 2021. The increase in interest income was due to the Company's investment in U.S. Treasury Bills and the resulting higher interest rates, as well as lower debt principal due to the conversion of a portion of the 2020 Secured Convertible Notes in May and November 2021. Additional information with respect to the Secured Notes is in Note 6 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 in this Quarterly Report.

*Nine Months Ended September 30, 2022 Compared to the Nine Months Ended September 30, 2021*

<i>(Dollars in thousands)</i>	Nine Months Ended September 30,		
	2022	2021	Percentage Change
Product revenue	\$ 9,750	\$ 8,863	10 %
Service and other revenue	5,627	3,154	78 %
Total revenue	15,377	12,017	28 %
Cost of revenue	5,162	4,078	27 %
Gross profit	10,215	7,939	29 %
Research and development costs	7,270	6,208	17 %
Sales and marketing expenses	6,171	5,061	22 %
General and administrative expenses	8,637	6,062	42 %
Other expense:			
Other expense, net	(22)	(60)	NM%
Interest expense, net	(165)	(809)	(80) %
Net loss	\$ (12,050)	\$ (10,261)	17 %

NM – The percentage change is not meaningful.

*Revenue.* Total revenue was \$15.4 million for the nine months ended September 30, 2022, and \$12.0 million for the nine months ended September 30, 2021, which represents an increase of \$3.4 million, or 28%.

<i>(in thousands)</i>	Nine Months Ended September 30,		
	2022	2021	Percentage Change
Functional neurosurgery navigation and therapy			
Disposable products	\$ 5,706	\$ 5,782	(1) %
Services	1,125	150	650 %
Subtotal – Functional neurosurgery navigation and therapy	6,831	5,932	15 %
Biologics and drug delivery			
Disposable products	2,873	2,501	15 %
Services	3,935	2,605	51 %
Subtotal – Biologics and drug delivery revenue	6,808	5,106	33 %
Capital equipment and software			
Systems and software products	1,171	580	102 %
Services	567	399	42 %
Subtotal – Capital equipment and software revenue	1,738	979	78 %
Total revenue	\$ 15,377	\$ 12,017	28 %

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 15% to \$6.8 million for the nine months ended September 30, 2022, from \$5.9 million for the same period in 2021. This increase reflects \$1.1 million of service revenue related to development services during the nine months ended September 30, 2022, compared to \$0.2 million service revenue for the same period in 2021, partially offset by a \$0.1 million decrease in product revenue.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 33% to \$6.8 million for the nine months ended September 30, 2022, from \$5.1 million for the same period in 2021. This increase is attributable to a \$1.3 million increase in service revenue as well as a \$0.4 million increase in product revenue related to new and continued partnerships with

pharmaceutical and biotech companies, academic institutions, and contract research organizations during the nine months ended September 30, 2022, compared to the same period in 2021.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, increased 78% to \$1.7 million for the nine months ended September 30, 2022, from \$1.0 million for the same period in 2021, due primarily to an increase in the placement of ClearPoint capital and software.

*Cost of Revenue and Gross Profit.* Cost of revenue was \$5.2 million, resulting in gross profit of \$10.2 million and gross margin of 66%, for the nine months ended September 30, 2022, and was \$4.1 million, resulting in gross profit of \$7.9 million and representing a gross margin of 66%, for the nine months ended September 30, 2021. Gross margin remained consistent during the nine months ended September 30, 2022, as compared to the same period in 2021. This was due to an increase in the excess and obsolete inventory reserve, which was fully offset by lower overhead expenses as well as an increased contribution of service revenue, which carries a higher gross margin relative to product revenue.

*Research and Development Costs.* Research and development costs were \$7.3 million for the nine months ended September 30, 2022, compared to \$6.2 million for the same period in 2021, an increase of \$1.1 million, or 17%. The increase was due primarily to increases in personnel costs of \$0.4 million due to growth in headcount, and product and software development of \$0.4 million, both resulting from our efforts to expand the applications of our technological platforms, as well as increases in regulatory consulting fees of \$0.2 million.

*Sales and Marketing Expenses.* Sales and marketing expenses were \$6.2 million for the nine months ended September 30, 2022, compared to \$5.1 million for the same period in 2021, an increase of \$1.1 million, or 22%. This increase was due primarily to additional personnel costs resulting from increases in headcount of \$0.6 million, increased marketing activities of \$0.2 million, and travel related costs of \$0.2 million.

*General and Administrative Expenses.* General and administrative expenses were \$8.6 million for the nine months ended September 30, 2022, compared to \$6.1 million for the same period in 2021, an increase of \$2.6 million, or 42%. This increase was due primarily to increased share-based compensation of \$1.8 million and personnel costs of \$0.8 million, both attributed to increases in headcount.

*Interest Expense.* Net interest expense for the nine months ended September 30, 2022 was \$0.2 million, compared to \$0.8 million for the same period in 2021, due to lower interest expense as a result of the conversion of a portion of the 2020 Secured Convertible Notes in May and November 2021. Additional information with respect to the Secured Notes is in Note 6 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 in this Quarterly Report. Interest expense was partially offset by higher interest income in the nine months ended September 30, 2022, as a result of increasing interest rates and the Company's investment in U.S. Treasury Bills.

#### **Liquidity and Capital Resources**

We have incurred net losses since our inception, which has resulted in a cumulative deficit at September 30, 2022 of \$146.0 million. In addition, our use of cash from operations amounted to \$13.1 million for the nine months ended September 30, 2022, and \$12.7 million for the year ended December 31, 2021. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable.

In January 2020, we entered into a Securities Purchase Agreement (the "SPA") with two investors (each, a "2020 Convertible Noteholder," and together, the "2020 Convertible Noteholders") under which we issued the first term notes (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.

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 a note (the "Second Closing Note," and together with the First Closing Notes, the "2020 Secured Notes"). On December 29, 2020, under the terms of an amendment to the SPA which, among other provisions, increased the principal amount of the Second Closing Note, we issued the Second Closing Note to one of the 2020 Convertible Noteholders in the principal amount of \$7.5 million.

See Note 6 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 in this Quarterly Report for additional information with respect to the 2020 Secured Notes.

As discussed in Note 8 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 in this Quarterly Report, 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.

As a result of these transactions and our business operations, our cash, cash equivalents, and short-term investments totaled \$40.5 million at September 30, 2022. In management's opinion, based on our current forecasts for revenue, expense and cash flows, our existing cash and cash equivalent balances and short-term investments at September 30, 2022, 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, 2022 and 2021 is summarized as follows:

<i>(in thousands)</i>	Nine months ended September 30,	
	2022	2021
Cash used in operating activities	(13,102)	\$ (9,145)
Cash used in investing activities	(22,482)	(130)
Cash provided by financing activities	187	46,827
Net change in cash and cash equivalents	<u>\$ (35,397)</u>	<u>\$ 37,552</u>

*Net Cash Flows from Operating Activities.* Net cash flows used in operating activities for the nine months ended September 30, 2022, were \$13.1 million, an increase of \$4.0 million from the nine months ended September 30, 2021. This increase consisted of a higher net loss of \$1.8 million and the effects of net changes of operating assets and liabilities of \$3.3 million, partially offset by a change in non-cash items of \$1.3 million. The change in operating assets and liabilities is primarily due to the use of cash for the buildup of inventory stock in response to supply chain disruptions and the change in the non-cash items results from increases in share-based compensation.

*Net Cash Flows from Investing Activities.* Net cash flows used in investing activities for the nine months ended September 30, 2022, were \$22.5 million and consisted primarily of the purchase of short-term marketable investments of \$21.6 million as well as equipment acquisitions and licensing rights.

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, 2022, consisted of proceeds of \$0.6 million from the exercise of common stock options and warrants and purchases made under the employee stock purchase plan, partially offset by payments of \$0.3 million for taxes related to shares withheld in connection with the vesting of restricted stock awards.

Net cash flows from financing activities for the nine months ended September 30, 2021, consisted of the proceeds, net offering costs, of \$46.8 million received from the public offering of our common stock, and 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 the vesting of restricted stock awards.

## 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 continue to 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 macroeconomic trends, including the COVID-19 pandemic, inflationary pressures and supply chain disruptions;
- the timing of broader market acceptance and adoption of our products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our products;
- the ability of our Partners to achieve commercial success, including their use of our products and services in their clinical trials and delivery of therapies;
- 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.

### **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, three to twelve month U.S. Treasury Bills, 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, 2022, we had \$10 million of principal outstanding under a First Closing Note, which is subject to interest rate fluctuations. The outstanding First Closing Note bears 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 Note. At September 30, 2022, the three-month LIBOR was greater than the 2% floor as a result of rising interest rates, and the rate paid on the outstanding First Closing Note was 5.6%. If the LIBOR continues to increase, a one-percent to two-percent increase would result in additional annual interest expense of \$0.3 million to \$0.4 million above the floor, respectively. Information with respect to the outstanding First Closing Note may be found in Note 6 to the Condensed Consolidated Financial Statements included above in Part I, Item 1 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, 2022 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, 2022.

#### **Changes in Internal Control Over Financial Reporting**

During the quarter ended September 30, 2022, 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.



## **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 2021 Form 10-K, except as set forth below.

**Our business, financial condition, and results of operations may be adversely affected by the current and future social and geopolitical instability and domestic and foreign economic instability.**

We are exposed to the risk of changes in social, geopolitical, legal, and economic conditions. The global economy has been, and may continue to be, negatively impacted by Russia's invasion of Ukraine in 2022. The negative impacts arising from the conflict and sanctions and export restrictions imposed by various countries, including those imposed by Russia, may include reduced consumer demand, supply chain disruptions, increased cybersecurity risks, and increased costs for transportation, energy, and raw materials. Although none of our operations are in Russia or Ukraine, further escalation of geopolitical tensions could have a broader impact that expands into other markets where we do business, which may adversely affect our business, financial condition and results of operations.

Further, changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause changes in fiscal and monetary policy. Additionally, our ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. Impacts from inflationary pressures, such as increasing costs for research and development of our products, administrative and other costs of doing business, could adversely affect our business, financial condition and results of operations.

Additionally, our customers could experience financial and operational pressures as a result of labor shortages, the supply chain disruptions, and increased inflation, which could impact their ability to access capital markets and other funding sources, increase cost of funding, or impede their ability to comply with debt covenants, which in turn could impede their ability to provide patient care, conduct further research and development, marketing and commercialization efforts, or impact their profitability. To the extent that our customers continue to face such financial pressures, it could impact their willingness to spend on our products and services, which could adversely affect our business, financial condition and results of operations.

### **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.

**ITEM 6. EXHIBITS.**

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

Exhibit Number	Exhibit Description
3.1	<a href="#">Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 11, 2012).</a>
3.2	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 8, 2015).</a>
3.3	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, filed with the SEC on August 2, 2016).</a>
3.4	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2020).</a>
3.5	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 26, 2022).</a>
3.6	<a href="#">Certificate of Correction of Certificate of Amendment of Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 6, 2022).</a>
3.7	<a href="#">Amended and Restated Bylaws of MRI Interventions, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 11, 2012).</a>
3.8	<a href="#">Second Amended and Restated Bylaws of ClearPoint Neuro, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2020).</a>
3.9	<a href="#">Third Amended and Restated Bylaws of ClearPoint Neuro, Inc. (incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on December 17, 2021).</a>
10.1	<a href="#">Employment Agreement, dated September 20, 2022, by and between the Company and Mazin Sabra (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 20, 2022).</a>
31.1*	<a href="#">Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</a>
31.2*	<a href="#">Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</a>
32+	<a href="#">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</a>
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.

**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 8, 2022

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, 2022, 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 8, 2022

/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, 2022, 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 8, 2022

/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 September 30, 2022, 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 8, 2022

/s/ Joseph M. Burnett

Joseph M. Burnett  
Chief Executive Officer

/s/ Danilo D'Alessandro

Danilo D'Alessandro  
Chief Financial Officer