REFINITIV

DELTA REPORT

10-Q

NVNO - ENVVENO MEDICAL CORP

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	407
CHANGES	4
DELETIONS	402
ADDITIONS	1

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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission file number: **001-38325**

enVVeno Medical Corporation

(Exact name of registrant as specified in its charter)

Delaware	**33-0936180**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

70 Doppler
Irvine, California92618
(Address of principal executive offices)

(949)261-2900
(Registrant's telephone number, including area code)

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

Title of Each Class:	**Name of Each Exchange on Which Registered:**	**Ticker Symbol**
Common Stock, $0.00001 par value	The NASDAQ Stock Market LLC	NVNO

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of October 23, 2023, there were 13,317,000 shares of common stock outstanding.

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ENVVENO MEDICAL CORPORATION
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PART I – FINANCIAL INFORMATION
ITEM 1 – Financial Statements

ENVVENO MEDICAL CORPORATION
CONDENSED BALANCE SHEETS
(Unaudited)

(In thousands except par values, unless otherwise indicated)	**September 30, 2023**	**December 31, 2022**
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,946	$ 4,555
Short-term investments	20,751	34,489
Prepaid expenses and other current assets	520	392
Total current assets	26,217	39,436
Property and equipment, net	385	521
Operating lease right-of-use assets, net	1,426	1,673
Security deposits and other assets	66	31
Total assets	$ 28,094	$ 41,661
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 1,700	$ 1,216
Current portion of operating lease liabilities	331	314
Total current liabilities	2,031	1,530
Long-term operating lease liabilities	1,148	1,402
Total liabilities	3,179	2,932
Commitments and Contingencies	-	-
Stockholders' Equity:		
Preferred stock, par value $0.00001, 10,000 shares authorized: no shares issued or outstanding	-	-
Common stock, par value $0.00001, 250,000 shares authorized, 9,472 shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Additional paid-in capital	149,302	145,249
Accumulated deficit	(124,387)	(106,520)
Total stockholders' equity	24,915	38,729
Total liabilities and stockholders' equity	$ 28,094	$ 41,661

See Notes to these Condensed Financial Statements

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ENVVENO MEDICAL CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
(In thousands, except per share data)				
Operating Expenses:				
Selling, general and administrative expenses	2,551	3,659	8,358	11,355
Research and development expenses	2,798	2,492	10,602	7,117
Loss from Operations	(5,349)	(6,151)	(18,960)	(18,472)
Other (Income) Expense:				
Realized (gain) from sales of trading securities	(148)	-	(398)	-
Unrealized (gain) loss from trading securities	(156)	21	(567)	134
Interest income, net	(44)	(75)	(128)	(117)
Total Other (Income) Expense	(348)	(54)	(1,093)	17
Net Loss	$ (5,001)	$ (6,097)	$ (17,867)	$ (18,489)
Net Loss Per Basic and Diluted Common Share:	$ (0.45)	(0.54)	(1.59)	(1.65)
Weighted Average Number of Common Shares Outstanding:				
Basic and Diluted	11,231	11,229	11,231	11,229

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ENVVENO MEDICAL CORPORATION
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, unless otherwise indicated)
(Unaudited)

	Three Months Ended September 30, 2023				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at July 1, 2023	9,472	-	$ 148,198	$ (119,386)	$ 28,812
Share-Based Compensation	-	-	1,104	-	1,104
Net loss	-	-	-	(5,001)	(5,001)
Balance at September 30, 2023	9,472	$ -	$ 149,302	$ (124,387)	$ 24,915

	Three Months Ended September 30, 2022				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at July 1, 2022	9,470	-	$ 140,801	$ (94,243)	$ 46,558
Share-Based Compensation	-	-	2,210	-	2,210
Net loss	-	-	-	(6,097)	(6,097)
Balance at September 30, 2022	9,470	$ -	$ 143,011	$ (100,340)	$ 42,671

	Nine Months Ended September 30, 2023				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2023	9,472	$ -	$ 145,249	$ (106,520)	$ 38,729
Share-Based Compensation	-	-	4,053	-	4,053
Net loss	-	-	-	(17,867)	(17,867)
Balance at September 30, 2023	9,472	$ -	$ 149,302	$ (124,387)	$ 24,915

	Nine Months Ended September 30, 2022				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2022	9,470	$ -	$ 136,255	$ (81,851)	$ 54,404
Share-Based Compensation	-	-	6,756	-	6,756
Net loss	-	-	-	(18,489)	(18,489)
Balance at September 30, 2022	9,470	$ -	$ 143,011	$ (100,340)	$ 42,671

See Notes to these Condensed Financial Statements

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ENVVENO MEDICAL CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands, unless otherwise indicated)
(Unaudited)

	For the Nine Months Ended September 30,	
	2023	**2022**
Cash Flows from Operating Activities		
Net loss	$ (17,867)	$ (18,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	4,052	6,756
Depreciation and amortization	165	158
Amortization of right-of-use assets	247	237
Unrealized (gain) loss from investments, net	(567)	134
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(155)	(69)
Security deposit and other assets	(8)	20
Accounts payable, accrued expenses and other current liabilities	484	(293)
Operating lease liabilities	(236)	(217)
Net Cash Used in Operating Activities	(13,885)	(11,763)
Cash Flows from Investing Activities		
Purchase of property and equipment	(29)	(106)
Purchases of investments	(24,276)	(42,214)
Maturities of investments	38,581	2,250
Net Cash Provided by (Used in) Investing Activities	14,276	(40,070)
Net Increase (Decrease) in Cash, Cash Equivalents	391	(51,833)
Cash, cash equivalents - Beginning of period	4,555	54,728
Cash, cash equivalents - End of period	$ 4,946	$ 2,895

See Notes to these Condensed Financial Statements

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ENVVENO MEDICAL CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS (Continued)
(In thousands, unless otherwise indicated)
(Unaudited)

	For the Nine Months Ended September 30,	
	2023	**2022**
Supplemental Disclosures of Cash Flow Information:		
Non-Cash Financing Activities:		
Fair value of warrants issued in satisfaction of trade payable	$ -	$ 130

See Notes to these Condensed Financial Statements

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ENVVENO MEDICAL CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1 – Business Organization and Nature of Operations

enVVeno Medical Corporation is a late clinical-stage med-tech company focused on the advancement of innovative bioprosthetic (tissue-based) solutions to improve the standard of care for the treatment of venous disease. The Company is developing surgical and non-surgical replacement venous valves for patients suffering from severe Chronic Venous Insufficiency (CVI) of the deep venous system of the leg. CVI most often occurs when valves inside the veins of the leg become damaged, resulting in the backwards flow of blood (reflux), blood pooling in the lower leg, increased pressure in the veins of the leg (venous hypertension) and in severe cases, venous ulcers that are difficult to heal. The Company's lead product is the VenoValve® which is currently being evaluated in a U.S. pivotal study.

The Company is also developing a second product called enVVe®, which is a transcatheter based replacement venous valve. Both the VenoValve and enVVe are designed to act as one-way valves, to help assist in propelling blood up the veins of the leg, and back to the heart and lungs.

The Company develops and manufactures its products in a 14,507 sq. ft. leased manufacturing facility in Irvine, California, which has been ISO 13485-2016 certified for the design, development and manufacturing of tissue based implantable medical devices.

Note 2 – Management's Liquidity Plan

The Company has incurred historical losses and operating cash outflows, expects to continue to do so for the foreseeable future, and may need to raise additional capital to sustain its operations, pursue its product development initiatives and penetrate markets for the sale of its products. Management believes that our capital resources at September 30, 2023 are sufficient to meet our obligations as they become due within one year after the date of this Quarterly Report.

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Note 3 – Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed financial statements of the Company as of September 30, 2023 and December 31, 2022, and for the three and nine months ended September 30, 2023 and 2022. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the operating results for the full year. These unaudited condensed financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2022 included in the Company's Form 10-K filed with the SEC on March 2, 2023. The condensed balance sheet as of December 31, 2022 has been derived from the Company's audited financial statements.

Note 4 – Investments

The components of investments were as follows at September 30, 2023 and December 31, 2022:

(In thousands)

	September 30, 2023		December 31, 2022	
	Cash Equivalents	Short-Term Investment	Cash Equivalents	Short-Term Investments
Fair Value Level 1				
U.S. Government securities	$ 4,678	$ 20,751	$ 4,040	$ 34,489
Total debt investments	$ 4,678	$ 20,751	$ 4,040	$ 34,489

Unrealized and realized gains and losses on the accompanying statement of operations result from fixed-income securities and are primarily attributable to changes in interest rates. Management does not believe any remaining unrealized losses represent impairments based on our evaluation of available evidence.

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Note 5 – Concentrations

The Company maintains cash with major financial institutions. Cash held in United States bank institutions is currently insured by the Federal Deposit Insurance Corporation ("FDIC") up to $0.25 million at each institution. There were aggregate uninsured cash balances of $4.7 million and $4.3 million as of September 30, 2023 and December 31, 2022, respectively.

Note 6 – Accounts Payable, Accrued Expenses and Other Current Liabilities

As of September 30, 2023, and December 31, 2022, accounts payable, accrued expenses and other current liabilities consist of the following:

(In thousands)	September 30, 2023	December 31, 2022
Accounts payable	$ 1,235	$ 648
Accrued compensation costs	360	391
Accrued professional fees	19	62
Other accrued expenses	86	115
Total accrued expenses and other current liabilities	$ 1,700	$ 1,216

Note 7 – Commitments and Contingencies

Litigations Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

Robert Rankin Complaints

On July 9, 2020, the Company was served with a civil complaint filed in the Superior Court for the State of California, County of Orange by a former employee, Robert Rankin, who resigned as the Company's Chief Financial Officer, Secretary, and Treasurer on March 30, 2020. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and was filed on May 27, 2020. The complaint asserts causes of action alleging failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement, Labor Code violations, and unfair competition, and seeks damages for back pay, unpaid wages, compensatory damages, punitive damages, and attorney's fees and costs.

On September 3, 2020 the Company and its Chief Executive Officer were served with a second complaint filed in the Superior Court for the State of California, County of Orange by Mr. Rankin. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857 and was filed on August 31, 2020. The second complaint asserts causes of action alleging defamation, Labor Code violations, sex-based discrimination, and unfair competition, and seeks damages for lost wages, emotional and mental distress, consequential damages, punitive damages, and attorney's fees and costs.

The Company denies all claims in both matters (which have now been consolidated), is vigorously defending same, and has asserted counterclaims against Mr. Rankin contending that he breached his fiduciary duty and employment agreement with the Company and the Company incurred damages as a result. The Company continues to believe it has meritorious defenses to both matters which are currently set for trial on October 30, 2023.

As of the date of these financial statements, the amount of loss associated with these complaints, if any, cannot be reasonably estimated. Accordingly, no amounts related to these complaints are accrued as of September 30, 2023.

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ENVVENO MEDICAL CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 8 –Stockholders' Equity

Stock Options

During the nine-months ended September 30, 2023, the Company granted options to employees for the purchase of one-hundred-ten thousand shares with a weighted average exercise price of $6.70 per share.

The Company recognized $4.1 million and $6.6 million of share-based compensation related to stock options during the nine months ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, there was $4.5 million of unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over the weighted average remaining vesting period of 1.3 years.

Note 9 – Net Loss per Share

The following table summarizes the number of potentially dilutive common stock equivalents excluded from the calculation of diluted net loss per common share as of September 30, 2023 and 2022:

	September 30,	
(In thousands)	**2023**	**2022**
Shares of common stock issuable upon exercise of warrants	4,506	4,570
Shares of common stock issuable upon exercise of options	4,254	3,838
Potentially dilutive common stock equivalents excluded from diluted net loss per share	8,760	8,408

Note 10 – Subsequent Events

On October 6, 2023, the Company entered into a Securities Purchase Agreement with certain investors. The transaction closed on October 11, 2023. The following table provides an overview of this transaction.

Date	**Description**	**Unit Type**	**Number of shares**	**Number of pre-funded warrants**	**Number of Tranche A Warrants**	**Number of Tranche B Warrants**	**Net Proceeds**
(In thousands)							
October 11, 2023	PIPE Offering	Common Stock, warrants and pre-funded warrants	3,845	978	4,823	4,823	$ 25,686

The purchase price was $5.806 for each unit consisting of one share of common stock (or one Pre-Funded Warrant in lieu thereof), one Tranche A Warrant and one Tranche B Warrant (the pre-funded warrants, Tranche A Warrants and Tranche B Warrants, collectively, the "Warrants").

The Warrants are immediately exercisable at an exercise price of $6.945 per share for the Tranche A Warrants, $8.334 per share for the Tranche B Warrants, and a nominal exercise price of $0.0001 per share for the Pre-Funded Warrants. The Tranche A Warrants will expire on the earlier of (i) the thirtieth (30th) calendar day following the release by the Company of initial top line efficacy data including rVCSS data constituting a 3 or more-point improvement for the SAVVE clinical trial or (ii) October 11, 2024. The Tranche B Warrants will expire on the earlier of (i) the thirtieth (30th) calendar day following the PMA Approval by the U.S. FDA for the VenoValve or (ii) October 12, 2026. The Pre-Funded Warrants will terminate when they are exercised in full.

The Company also issued to the placement agent in the transaction warrants to purchase 241,000 shares of Common Stock at an exercise price of $6.945 which expire on October 11, 2028.

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Item 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our unaudited condensed financial statements and notes thereto included herein. In connection with, and because we desire to take advantage of, the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, we caution readers regarding certain forward-looking statements in the following discussion and elsewhere in this report and in any other statement made by, or on our behalf, whether or not in future filings with the Securities and Exchange Commission. Forward-looking statements are statements not based on historical information and which relate to future operations, strategies, financial results or other developments. Such forward-looking statements involve significant risks and uncertainties. Forward looking statements are necessarily based upon estimates and assumptions that are inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and many of which, with respect to future business decisions, are subject to change. These uncertainties and contingencies can affect actual results and could cause actual results to differ materially from those expressed in any forward-looking statements made by, or on our behalf. Such statements include, without limitation, statements related to the exercise of the warrants issued in our recent private placement transaction and receipt the proceeds therefrom, our ability to utilize cash on hand (including the funds from our recent private placement) to fund operations well past several significant milestones, our ability to achieve the various milestones indicated herein and other statements identified by words such as "anticipate," "estimate," "plan," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions are used to identify forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Quarterly Report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Unless the context requires otherwise, references in this document to "NVNO", "we", "our", "us" or the "Company" are to enVVeno Medical Corporation.

Overview

enVVeno Medical Corporation is a late clinical-stage medical device company focused on the advancement of innovative bioprosthetic (tissue-based) solutions to improve the standard of care for the treatment of venous disease. Chronic Venous Disease (CVD) is the world's most prevalent chronic disease, impacting approximately 71% of the adult population of the U.S. Chronic Venous Insufficiency (CVI), is a large subset of CVD, which most often occurs when valves inside of the veins of the leg become damaged, resulting in the backwards flow of blood (reflux), blood pooling in the lower leg, increased pressure in the veins of the leg (venous hypertension) and in severe cases, venous ulcers that are difficult to heal. The Company is developing surgical and non-surgical replacement venous valves for patients suffering from severe CVI of the deep venous system of the leg.

The Company's lead product is the VenoValve®, which is a first-in-class surgical replacement venous valve that is currently being evaluated in a U.S. pivotal study. The Company is also developing a second product called enVVe®, which is a first-in-class, non-surgical, transcatheter based replacement venous valve. The Company is currently conducting pre-clinical testing on enVVe. Both the VenoValve and enVVe are designed to act as one-way valves, to help assist in propelling blood up the veins of the leg, and back to the heart and lungs.

The VenoValve and enVVe are being developed first for approval by the U.S. Food and Drug Administration (FDA). We expect the VenoValve to be eligible for FDA approval first, followed two to three years later by enVVe. If approved, we expect the VenoValve and enVVe to co-exist, with the VenoValve as a surgical replacement venous valve option and enVVe as a non-surgical replacement venous valve option, although we cannot provide any assurance that either the VenoValve or enVVe will receive approval from the FDA (see the section entitled "Risk Factors" in our Annual Report on Form 10-K). There are currently no devices approved as surgical or non-surgical replacement venous valves, and there are currently no effective treatments for deep venous CVI caused by incompetent valves.

Our team of officers and directors has been affiliated with numerous medical devices that have received FDA approval or CE marking and that have been commercially successful. We develop and manufacture our products in a 14,507 sq. ft. leased manufacturing facility in Irvine, California, which has been ISO 13485-2016 certified for the design, development and manufacturing of tissue based implantable medical devices.

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CVI Background

Chronic venous disease ("CVD") is the world's most prevalent chronic disease. CVD is generally classified using a standardized system known as CEAP (clinical, etiological, anatomical, and pathophysiological). The CEAP system consists of seven clinical classifications (C0 to C6) with C4, C5 and C6 being the most severe categories of CVD.

Chronic Venous Insufficiency ("CVI") is a large subset of CVD and is generally used to describe patients with C4 to C6 CVD. CVI is a debilitating condition that affects the venous system of the leg causing pain, swelling, edema, skin changes, and ulcerations.

The human leg contains three vein systems: the deep vein system, the superficial vein system, and the perforator vein system which connects the deep system to the superficial system. The deep venous system is located below the muscle and facia in the center portion of the leg and is responsible for approximately 90% of the blood flow. In order for blood to return to the heart from the foot, ankle, and lower leg, the calf muscle serves as a pump and pushes the blood up the veins of the leg against gravity and through a series of one-way valves. Each valve is supposed to open as blood passes through, and then close as blood progresses up the veins of the leg to the next valve. CVI occurs when the one-way valves in the veins of the leg fail and become incompetent. When the valves fail, gravity causes the blood to flow backwards and in the wrong direction (reflux). As blood pools in the lower leg, pressure inside the veins increases (venous hypertension). Reflux, and the resulting venous hypertension, causes the leg to swell, resulting in debilitating pain, and in the most severe cases, venous ulcers.

Severe CVI sufferers experience a significantly reduced quality of life. Daily activities such as preparing meals, housework, and personal hygiene (washing and bathing) become difficult due to reduced mobility. For many severe CVI sufferers, intense pain, which frequently occurs at night, prevents patients from getting adequate sleep. Severe CVI sufferers are known to miss approximately 40% more workdays than the average worker. A high percentage of venous ulcer patients also experience severe itching, leg swelling, and an odorous discharge. Wound dressing changes, which occur several times a week, can be extremely painful. Venous ulcers from deep venous CVI are very difficult to heal, and a significant percentage of venous ulcers remain unhealed for more than a year. Even if healed, recurrence rates for venous ulcers are known to be high (20% to 40%) within the first year and as high as 60% after five years. Patients with severe CVI often become housebound and experience social isolation due to difficulty with ambulation. As a result, studies have shown that patients with active venous ulcers experience higher rates of anxiety and depression, with reported rates of anxiety of up to 30% and depression up to 40%. Rates of depression caused by venous ulcers among the elderly are even higher, with 48% of elderly venous ulcer patients having severe depressive symptoms.

Prevalence is generally defined as the portion of the population that has a given condition. Estimates indicate that the prevalence of people in the U.S. with severe, deep venous CVI (C4 to C6 disease) with reflux to be approximately 20 million. Incidence is generally defined as the number of new cases of an ailment that develop in a given time period. We estimate that approximately 3.5 million new patients with severe deep venous CVI are diagnosed each year in the U.S. including patients that develop venous leg ulcers (C6 patients). The average patient seeking treatment of a venous ulcer spends as much as $30,000 a year on wound care, and the total direct medical costs from venous ulcer sufferers in the U.S. has been estimated to exceed $3 billion a year.

VenoValve

The VenoValve® is a porcine based replacement venous valve developed at enVVeno Medical to be surgically implanted in the deep venous system of the leg to treat severe CVI caused by valvular incompetence. By reducing reflux and lowering pressure (venous hypertension) within the deep venous system of the leg, the VenoValve has the potential to reduce or eliminate the symptoms of severe deep venous CVI, including the potential to heal recurring venous leg ulcers. The VenoValve is implanted into the femoral vein of the patient in an open surgical procedure via a 5-to-6-inch incision in the upper thigh. As our planned initial entrant to the replacement venous valve market, we estimate that approximately 2.5 million people with severe deep venous CVI in the U.S. would be candidates for the VenoValve.

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VenoValve Clinical Status

After consultation with the FDA, and as a precursor to the U.S. pivotal trial, in 2020 we conducted a small first-in-human study for the VenoValve in Colombia which included eleven (11) patients. The purpose of the first-in-human study was to provide proof of concept, and to provide feedback to make any necessary product modifications or adjustments to our surgical implantation procedure for the VenoValve prior to conducting the VenoValve pivotal trial. Endpoints for the VenoValve first-in-human study included safety (device related adverse events), reflux time, measured by Duplex Ultrasound, rVCSS scoring, which is a measurement created by international vascular societies and is used by the clinician to measure disease progression and regression a VAS score used by the patient to measure pain, and quality of life measurements.

Results from the one year first-in-human study were presented at the Charing Cross International Symposium in April of 2021. Among the eleven (11) patients in the study, reflux time improved an average of 54%, Venous Clinical Severity Scores ("VCSSs") improved an average of 56%, and visual analog scale (VAS) scores, which are used by patients to measure pain, improved an average of 76%, all at one (1) year when compared to pre-surgery levels. VCSS scores are a validated measurement commonly used to objectively assess outcomes in the treatment of venous disease, and include ten characteristics including pain, inflammation, skin changes such as pigmentation and induration, the number of active ulcers, and ulcer duration. The improvement in VCSS scores is significant and indicates the VenoValve patients who had severe CVI pre-surgery, had mild CVI or the complete absence of disease at one-year post surgery.

Related safety incidences during the one year first-in-human study for the VenoValve included one (1) fluid pocket (which was aspirated), intolerance from Coumadin anticoagulation therapy, three (3) minor wound infections (treated with antibiotics), and one occlusion due to patient non-compliance with anti-coagulation therapy.

At the end of the VenoValve first-in-human study, eight (8) study participants agreed to additional monitoring. In November of 2022, three-year follow-up data was presented for this cohort of patients at the 49th Annual VEITH Symposium in New York city.

On August 3, 2020, we announced that the FDA granted Breakthrough Device Designation status to the VenoValve. The FDA's Breakthrough Devices Program was established to enable priority review for devices that provide more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions. The goal of the FDA's Breakthrough Devices Program is to provide patients and health care providers with timely access to medical devices by speeding up their development, assessment, and review, while preserving the FDA's mission to protect and promote public health.

In March 2021, we submitted an IDE application with the FDA and in April 2021, we received notification from the FDA that our IDE application was approved. An investigational device exemption or IDE from the FDA is required before a medical device company can proceed with a pivotal trial for a Class III medical device. This approval allowed us to proceed with our U.S. pivotal study for the VenoValve which is called the SAVVE -(Surgical Anti-reflux Venous Valve Endoprosthesis) clinical study. The SAVVE study is a prospective, non-blinded, single arm, multi-center study of seventy-five (75) CVI patients to be enrolled at up to 30 U.S. sites.

Efficacy endpoints for the SAVVE pivotal study include rVCSS scores, which will be used to provide evidence of clinical meaningful benefit, as well as reflux time measurements, VAS pain scores, quality of life measurements, ulcer healing (for CEAP class C6 patients), and intra-operative and one-year vein patency and valve functionality. Safety endpoints include device related events including mortality, pulmonary embolism, and ipsilateral deep vein thrombosis, and procedure related events including infection and bleeding.

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The first patient in the SAVVE pivotal study was enrolled in October of 2021. Following enrollment of the first patient the SAVVE study was delayed due to COVID-19 restrictions. In November of 2022, we announced we had passed a preliminary safety review by the FDA for the first twenty (20) patients enrolled in the SAVVE trial. The FDA had requested that we submit preliminary safety data at thirty (30) days post VenoValve® implantation for the first twenty (20) patients enrolled in the study. The preliminary safety data included one (1) device related (mild) and two (2) procedure related (moderate) adverse events. After review by the FDA, the study was cleared to continue without modification or interruption.

On October 6, 2023, we announced we had achieved full enrollment (75 subjects) in the SAVVE trial, having enrolled eighteen (18) patients over the final two (2) months of the study. Full enrollment occurred approximately four (4) months earlier than expected due to increased demand for the VenoValve. The Company expects to release initial, topline safety data from the SAVVE study in Q4 of 2023, and initial, topline rVCSS efficacy data from the SAVVE study in Q2 of 2024. With the FDA indicating that one-year data for all 75 patients will be necessary prior to the filing of the application seeking pre-market (PMA) approval for the VenoValve, the Company will be eligible to file the PMA application seeking approval in Q4 of 2024.

enVVe

On September 21, 2022, we announced the development of a non-surgical transcatheter based replacement venous valve called enVVe®, for the treatment of CVI of the deep veins of the leg. Initial preliminary bench testing and pre-clinical testing for enVVe have been successfully completed.

On October 6, 2023, contemporaneously with the announcement of a Twenty-eight-million-dollar capital raise, we announced plans to expedite the development of enVVe. The Company expects to begin a six (6) month GLP animal study for enVVe in the first quarter of 2024 and to be ready to file for IDE approval for the enVVe pivotal trial by the end of 2024.

enVVe is delivered into the femoral vein of the patient via a minimally invasive procedure requiring no general anesthesia and no overnight hospital stay. Due to the minimally invasive nature of the procedure, we expect to be able to reach patients with less severe CVI or who may otherwise not be good candidates for a surgical device, and estimate the U.S. market for enVVe to be approximately 3.5 million patients.

Capital

We finished 2022 with approximately $39.1 million of cash and investments and had approximately $25.7 million of cash and investments at September 30, 2023.

On October 11, 2023, we closed an offering raising approximately $25.7 million net cash proceeds. This financing has the potential to fund the Company through several significant milestones, including the release of initial topline efficacy data from SAVVE, our anticipated FDA pre-market approval of the VenoValve, the beginning of preparations for VenoValve commercialization, and accelerated plans for the pivotal trial for enVVe, our transcatheter based replacement venous valve. Although we expect our quarterly cash burn rate will increase over time to support these milestones, after the additional proceeds from our offering, we believe we have sufficient cash to fund operations past what we expect will be regulatory approval of the VenoValve and the start of the enVVe pivotal trial.

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Comparison of the three months ended September 30, 2023 and 2022

Overview

We reported net losses of $5.0 million and $6.1 million for the three months ended September 30, 2023 and 2022, respectively, representing a decrease in net loss of $1.1 million or 18%, due to a decrease in operating expenses of $0.8 million, and a net increase in other income and expense of $0.3 million.

Revenues

As a developmental stage Company, we are not currently generating revenue and our future revenue, if any, is expected to be diminutive in the near future and dependent on our ability to commercialize our product candidates.

Selling, General and Administrative Expenses

For the three months ended September 30, 2023, selling, general and administrative expenses decreased by $1.1 million or 30%, to $2.6 million from $3.7 million for the three months ended September 30, 2022. This decrease was due to share-based compensation reflecting the reduction in expense from grants made during 2021, the cost for portions of which have been fully recognized.

Research and Development Expenses

For the three months ended September 30, 2023, research and development expenses increased by $0.3 million or 12%, to $2.8 million from $2.5 million for the three months ended September 30, 2022. This increase primarily resulted from $0.2 million in increased personnel costs to support the SAVVE study, and $0.1 million in lab costs, also to support the SAVVE study and continued product development.

Other (Income) Expense

For the three months ended September 30, 2023, other (income) expense increased $0.2 million from $0.1 million in net expense for the three months ended September 30, 2022 to $0.3 million other income for the three months ended September 30, 2023. Other (income) expense is primarily related to interest income and realized gains and unrealized (gain)/loss from investments reflecting the Company's investment activities in US Treasuries including realized gains, interest income and unrealized gains and losses resulting from changes in market value of the US Treasuries purchased by the Company. The increase reflects higher yields realized for the three months ended September 30, 2023 due to changes in interest rates resulting from recent US Federal Reserve actions. We expect the market value of these investments to fluctuate somewhat during their term, however all these Treasuries were purchased to provide a positive yield over their term.

Comparison of the nine months ended September 30, 2023 and 2022

Overview

We reported net losses of $17.9 million and $18.5 million for the nine months ended September 30, 2023 and 2022, respectively, representing a decrease in net loss of $0.6 million, or 3%, due to a decrease in operating expenses of $0.5 million, and an increase in other income and expense, net, of $1.1 million.

Revenues

As a developmental stage Company, we are not currently generating revenue and our future revenue, if any, is expected to be diminutive in the near future and dependent on our ability to commercialize our product candidates.

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Selling, General and Administrative Expenses

For the nine months ended September 30, 2023, selling, general and administrative expenses decreased $3.0 million or 26%, to $8.4 million from $11.4 million for the nine months ended September 30, 2022. Of this decrease, $2.7 million was due to a reduction in share-based compensation reflecting the reduction in expense from grants made during 2021, the cost for portions of which have been fully recognized.

The remaining $0.3 million decrease is attributable to $0.2 million from lower patent related legal costs, and $0.1 million from lower insurance costs related to decreased costs for cyber risk and D&O insurance premiums driven by an improving insurance market.

Research and Development Expenses

For the nine months ended September 30, 2023, research and development expenses increased by $3.5 million or 49%, to $10.6 million from $7.1 million for the nine months ended September 30, 2022.

This increase primarily resulted from $2.5 million in costs related the SAVVE study, $0.8 million higher compensation cost due to increases in staffing, $0.2 million in travel cost and $0.1 million in lab costs, both to support the SAVVE study and VenoValve continued development.

Other (Income) Expense

For the nine months ended September 30, 2023, other (income) expense increased $1.1 million from less than $0.1 million in other (income) expense for the nine months ended September 30, 2022 to $1.1 million other income for the nine months ended September 30, 2023. Other (income) expense is primarily related to interest income and realized gains and unrealized (gain)/loss from investments reflecting the Company's investment activities in US Treasuries including realized gains, interest income and unrealized gains and losses resulting from changes in market value of the US Treasuries purchased by the Company. The increase reflects higher yields realized for the nine months ended September 30, 2023 due to changes in interest rates resulting from recent US Federal Reserve actions. We expect the market value of these investments to fluctuate somewhat during their term, however all these Treasuries were purchased to provide a positive yield over their term.

Liquidity and Capital Resources

For the nine-months ended September 30, 2023, the Company incurred a net loss of $17.9 million and used $13.9 million cash in operating activities. Net cash used in operating activities for the period ended September 30, 2023 increased by $2.1 million from $11.8 million for the period ended September 30, 2022.

The losses and the uses of cash are primarily due to the Company's administrative and product research and development activities. Administrative functions relate to costs to support the Company's public reporting and investor relations activities as well as internal administrative functions. Research and development activities are for continued product development and clinical trials for our product candidates, currently the VenoValve® and enVVe®. The Company will continue to incur these costs to complete its clinical trials, enhance products, develop new products, and operate as a public company. Although we have discretion in how we use the Company's cash resources, we expect to continue these activities for the foreseeable future as we seek to obtain regulatory approval for our product candidates. We are not currently generating revenue and do not expect significant revenue until we successfully commercialize one or more of our product candidates.

Our cash flows from investing activity consist of maturities and purchases of US Treasury bills from our program to invest excess cash, and purchases of property and equipment for our lab and offices. During the nine months ended September 30, 2023 we purchased $24.3 million of treasury bills and $38.6 million of them matured generating $0.5 million in realized gains and interest income. We expect to continue investing as the treasury bills mature and as allowed by the cash requirements of our operations. In the nine months ended September 30, 2023, our purchases of property and equipment consisting primarily of lab and test equipment, were less than $0.1 million.

We do not currently have material commitments for capital expenditures or other expenditures except for our facility lease commitment of $0.4 million per year. However, we expect a modest increase in purchases of property and equipment as we continue SAVVE, plan for commercialization of the VenoValve and continue development of enVVe. Our future capital requirements will remain dependent upon a variety of factors, especially including the success of our clinical trials and related product development costs and our ability to successfully bring products to market.

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The Company has historically funded its operations through financing activities. On October 11, 2023, we closed an offering issuing stock and warrants and raising approximately $25.7 million net cash proceeds. Based upon our cash and working capital as of September 30, 2023, and after considering the transaction closed on October 11, 2023, we have sufficient capital resources to meet our obligations as they become due for at least one year after the date of this Report and sustain operations.

As of October 23, 2023, we had a cash and investment balances of $1.9 million and $48.6 million, respectively.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

As a smaller reporting company, we are not required to provide the information requested by paragraph (a)(5) of this Item.

Critical Accounting Policies and Estimates

For a description of our critical accounting policies, see Note 3 – Significant Accounting Policies in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

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Item 3. Quantitative and Qualitative Disclosure About Market Risk

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide information required by this Item.

Item 4: Controls and Procedures

Disclosure Controls and Procedures

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of September 30, 2023, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2023.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2023, there were no changes in our internal controls over financial reporting, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be subject to litigation and arbitration claims incidental to its business. Such claims may not be covered by our insurance coverage, and even if they are, if claims against us are successful, they may exceed the limits of applicable insurance coverage.

On July 9, 2020, the Company was served with a civil complaint filed in the Superior Court for the State of California, County of Orange by a former employee, Robert Rankin, who resigned as the Company's Chief Financial Officer, Secretary, and Treasurer on March 30, 2020. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and was filed on May 27, 2020. The complaint asserts causes of action alleging failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement, Labor Code violations, and unfair competition, and seeks damages for back pay, unpaid wages, compensatory damages, punitive damages, and attorney's fees and costs.

On September 3, 2020 the Company and its Chief Executive Officer were served with a second complaint filed in the Superior Court for the State of California, County of Orange by Mr. Rankin. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857 and was filed on August 31, 2020. The second complaint asserts causes of action alleging defamation, Labor Code violations, sex-based discrimination, and unfair competition, and seeks damages for lost wages, emotional and mental distress, consequential damages, punitive damages, and attorney's fees and costs.

The Company denies all claims in both matters (which have now been consolidated), is vigorously defending same, and has asserted counterclaims against Mr. Rankin contending that he breached his fiduciary duty and employment agreement with the Company and the Company incurred damages as a result. The Company continues to believe it has meritorious defenses to both matters, which are currently set for trial on October 30, 2023.

Item 1A. Risk Factors

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide information required by this Item. Our current risk factors are set forth in our Form 10-K, filed with the SEC on March 2, 2023.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine and Safety Disclosure

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

The following is a complete list of exhibits filed as part of this Form 10-Q. Exhibit numbers correspond to the numbers in the Exhibit Table of Item 601 of Regulation S-K.

Exhibit	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act. *
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Sarbanes-Oxley Act. *
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act**
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** **Furnished herewith.**

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SIGNATURES

Pursuant to the requirements of Section 12 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: October 25, 2023

ENVVENO MEDICAL CORPORATION

By: */s/ Robert Berman*

Robert Berman
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Craig Glynn*

Craig Glynn
Chief Financial Officer
(Principal Financing and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert Berman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of enVVeno Medical Corporation;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its 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

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

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

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

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

October 25, 2023 May 8, 2024

/s/ Robert Berman

Name: Robert Berman
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE
SECURITIES EXCHANGE ACT OF 1934

I, Craig Glynn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of enVVeno Medical Corporation;

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

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

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

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

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

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

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

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

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

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

October 25, 2023 May 8, 2024

/s/ Craig Glynn

Name: Craig Glynn
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of enVVeno Medical Corporation (the "Company's Quarterly Report") on Form 10-Q for the period ended September 30, 2023 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Robert Berman, as Chief Executive Officer and principal executive officer and Craig Glynn, as Chief Financial Officer and principal financial officer of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of the undersigned's knowledge and belief, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

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REFINITIV

/s/ Robert Berman

Robert Berman
Chief Executive Officer and Principal Executive Officer

Dated: October 25, 2023 May 8, 2024

/s/ Craig Glynn

Craig Glynn
Chief Financial Officer and Principal Financial Officer

Dated: October 25, 2023 May 8, 2024

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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