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 June 30, 2024

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, California 92618
(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 July 29, 2024, there were 13,330,000 shares of common stock outstanding.

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)	June 30, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,380	$ 3,620
Short-term investments	36,687	42,792
Prepaid expenses and other current assets	469	511
Total Current Assets	39,536	46,923
Property and equipment, net	252	334
Operating lease right-of-use assets, net	1,176	1,347
Security deposits and other assets	31	31
Total Assets	$ 40,995	$ 48,635
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 1,344	$ 1,033
Current portion of operating lease liabilities	351	338
Total Current Liabilities	1,695	1,371
Long-term operating lease liabilities	882	1,064
Total Liabilities	2,577	2,435
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, 13,330 and 13,317 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	-	-
Additional paid-in capital	178,402	176,236
Accumulated deficit	(139,984)	(130,036)
Total Stockholders' Equity	38,418	46,200
Total Liabilities and Stockholders' Equity	$ 40,995	$ 48,635

See Notes to these Unaudited Condensed Financial Statements

ENVVENO MEDICAL CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
(In thousands, except per share data)				
Operating Expenses:				
Selling, general and administrative expenses	2,629	2,600	5,080	5,805
Research and development expenses	2,825	4,214	5,877	7,806
Loss from Operations	(5,454)	(6,814)	(10,957)	(13,611)
Other Income:				
Realized gains from sales of trading securities	379	168	787	250
Unrealized gains from of trading securities	46	133	90	411
Interest income, net	73	39	132	84
Total Other Income	498	340	1,009	745
Net Loss	$ (4,956)	$ (6,474)	$ (9,948)	$ (12,866)
Net Loss Per Basic and Diluted Common Share:	$ (0.31)	$ (0.58)	$ (0.62)	$ (1.15)
Weighted Average Number of Common Shares Outstanding:				
Basic and Diluted	16,067	11,231	16,062	11,231

See Notes to these Unaudited Condensed Financial Statements

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

	Three Months Ended June 30, 2024				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at April 1, 2024	13,330	-	$ 177,397	$ (135,028)	$ 42,369
Shared-Based Compensation	-	-	1,005	-	1,005
Net loss	-	-	-	(4,956)	(4,956)
Balance at June 30, 2024	13,330	$ -	$ 178,402	$ (139,984)	$ 38,418

	Three Months Ended June 30, 2023				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at April 1, 2023	9,472	-	$ 147,041	$ (112,912)	$ 34,129
Shared-Based Compensation	-	-	1,157	-	1,157
Net loss	-	-	-	(6,474)	(6,474)
Balance at June 30, 2023	9,472	$ -	$ 148,198	$ (119,386)	$ 28,812

	Six Months Ended June 30, 2024				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2024	13,317	$ -	$ 176,236	$ (130,036)	$ 46,200
Shared-Based Compensation	-	-	2,120	-	2,120
Options exercised	13	-	46	-	46
Net loss	-	-	-	(9,948)	(9,948)
Balance at June 30, 2024	13,330	$ -	$ 178,402	$ (139,984)	$ 38,418

	Six Months Ended June 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
Shared-Based Compensation	-	-	2,949	-	2,949
Net loss	-	-	-	(12,866)	(12,866)
Balance at June 30, 2023	9,472	$ -	$ 148,198	$ (119,386)	$ 28,812

See Notes to these Unaudited Condensed Financial Statements

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

	For the Six Months Ended June 30,

	2024	2023
Cash Flows from Operating Activities		
Net loss	$ (9,948)	$ (12,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	2,120	2,949
Depreciation and amortization	106	109
Amortization of right of use assets	171	165
Unrealized (gain) loss from investments	(90)	(411)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	42	40
Accounts payable	271	656
Accrued expenses and other current liabilities	40	(157)
Operating lease liabilities	(169)	(157)
Net Cash Used in Operating Activities	(7,457)	(9,672)
Cash Flows from Investing Activities		
Maturities of investments	31,263	24,956
Purchase of property and equipment	(24)	(26)
Purchases of investments	(25,068)	(15,099)
Net Cash Provided by Investing Activities	6,171	9,831
Cash Flows from Financing Activities		
Proceeds from Stock Option Exercises	46	-
Net Cash Provided by Financing Activities	46	-
Net (Decrease) Increase in Cash	(1,240)	159
Cash, cash equivalents - Beginning of period	3,620	4,555
Cash, cash equivalents - End of period	2,380	$ 4,714

See Notes to these Unaudited Condensed Financial Statements

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 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. 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.

The Company's lead product is the VenoValve®, which is a potential 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 potential first-in-class, non-surgical, transcatheter based replacement venous valve system consisting of the enVVe valve, the enVVe delivery system, and the delivery system accessories. 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.

Note 2 – Management's Liquidity Plan

As of June 30, 2024, the Company had a cash and investment balance of $ 39.1 million and working capital of $ 37.8 million. Although the Company expects to continue incurring losses 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 are sufficient to meet our obligations as they become due within one year after the date of this Quarterly Report, and sustain operations.

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 June 30, 2024 and December 31, 2023, and for the three and six months ended June 30, 2024 and 2023.

The results of operations for the three and six months ended June 30, 2024 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, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2024. The accompanying condensed balance sheet as of December 31, 2023 has been derived from the Company's audited financial statements.

ENVVENO MEDICAL CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 4 – Investments

The components of investments at June 30, 2024 and December 31, 2023 were as follows:

(In thousands)

	June 30, 2024		December 31, 2023	
	Cash Equivalents	Short-Term Investment	Cash Equivalents	Short-Term Investments
Fair Value Level 1				
U.S. Government securities	$ 1,661	$ 36,687	$ 3,187	$ 42,792
Total debt investments	$ 1,661	$ 36,687	$ 3,187	$ 42,792

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.

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 $250,000 at each institution. There were aggregate uninsured cash balances of $ 0.9 million and $ 3.4 million as of June 30, 2024 and December 31, 2023, respectively.

Note 6 – Accounts Payable Accrued Expenses and Other Current Liabilities

As of June 30, 2024, and December 31, 2023, accounts payable, accrued expenses and other current liabilities consist of the following:

(In thousands)	June 30, 2024	December 31, 2023
Accounts payable	$ 698	$ 427
Accrued compensation costs	517	478
Other accrued expenses	129	128
Total accrued expenses and other current liabilities	$ 1,344	$ 1,033

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 his employment on or about 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. 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 complaints allege several causes of action including a cause of action for failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement, defamation, unlawful 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 has denied all claims in both matters (which have now been consolidated) and has filed a counterclaim asserting that Rankin has breached his employment agreement with the Company and fiduciary duty to the Company's damage. The Company continues to believe it has meritorious defenses to both matters which are currently set for trial on August 12, 2024.

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 June 30, 2024.

Note 8 –Stockholders' Equity

Stock Options

Stock-based compensation is reflected in selling, general and administrative expenses in the accompanying condensed statements of operations and was $1.0 million and $ 1.2 million during the three months ended June 30, 2024 and 2023, respectively, and $ 2.1 million and $ 3.0 million during the six months ended June 30, 2024 and 2023. As of June 30, 2024, there was $ 5.3 million of unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over the weighted average remaining vesting period of 1.5 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 June 30, 2024 and 2023:

(In thousands)	June 30,	
	2024	2023
Shares of common stock issuable upon exercise of warrants	9,546	4,513
Shares of common stock issuable upon exercise of options	5,554	4,269
Potentially dilutive common stock equivalents excluded from diluted net loss per share	15,100	8,782

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 Quarterly 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. 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 70% 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 potential first-in-class surgical replacement venous valve that is currently being evaluated in a U.S. pivotal study called the SAVVE trial (Surgical Anti-reflux Venous Valve Endoprosthesis). To date, patients in our SAVVE trial have indicated in testimonials to the Company that they have experienced reduced pain and enhanced quality of life as a result of the VenoValve.

The Company is also developing a second product called enVVe®, which is a potential, non-surgical, transcatheter based replacement venous valve system consisting of the enVVe valve, the enVVe delivery system, and the delivery system accessories. The Company is conducting pre-clinical testing on enVVe and currently expects to be ready to file for IDE approval for the enVVe pivotal trial (the Transcatheter Anti-Thrombotic, Venous Valve Endoprosthesis or TAVVE) in Q2 of 2025.

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 to be eligible to file for FDA approval of the VenoValve in the fourth quarter of 2024 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. 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 both the VenoValve and EnVVe in a 14,000 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.

CVI Background

Chronic venous disease (CVD) is the world's most prevalent chronic disease. CVD is clinically 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 them 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 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 each year with severe deep venous CVI in the U.S. would be candidates for the VenoValve. The VenoValve has been granted Breakthrough Device designation by the FDA.

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.

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, revised Venous Clinical Severity Scores (rVCSS) scores improved an average of 6 points, and patients also experienced significant improvements in pain (measured via visual analog scale (“VAS”) scores), and quality of life (measured by Veines sym/qol) all at one (1) year when compared to pre-surgery levels. Revised Venous Clinical Severity Scoring (rVCSS) is a validated measurement commonly used to objectively assess outcomes in the treatment of venous disease, and include ten characteristics consisting of physician assessments and patient reported outcomes including pain, inflammation, skin changes such as pigmentation and induration, the number of active ulcers, and ulcer duration. The improvement in VCSS scores was 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) surgical pocket hematoma (anti-coagulation related bleeding outside of the target vein within the surgical cavity), 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.

Three (3) year results from eight (8) first-in-human study participants who agreed to additional monitoring were presented at the February 2023 annual meeting of the American Venous Forum in San Antonio, Texas. Patients continued to show significant clinical improvement (average 8 point rVCSS improvement compared to baseline) at three (3) years post-VenoValve surgery, with no venous ulcer recurrences for C6 patients.

In March of 2021 we received IDE approval from the FDA to begin the VenoValve pivotal study. 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 enrolled at 21 U.S. sites.

Efficacy endpoints for the SAVVE pivotal study include rVCSS scores, which are used to provide evidence of clinically 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 and procedure related events including mortality, pulmonary embolism, ipsilateral deep vein thrombosis, infection and bleeding.

We achieved full enrollment of 75 subjects in the SAVVE trial on September 1, 2023, 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.

On November 16, 2023, we presented preliminary device related thirty-day Device Related Material Adverse Event (“MAE”) data at the 50th Annual VEITH Symposium. The preliminary device related MAE rate for the fully enrolled 75 subject study was eight percent (8%). MAEs for the SAVVE study are defined as all-cause mortality, pulmonary embolisms (“PEs”), ipsilateral deep vein thromboses (“DVTs”), bleeding, and deep wound infections, occurring within thirty (30) days of enrollment in the study, being either device or procedure related. The device related MAEs presented at the conference indicated no deaths, no pulmonary embolisms, and six (6) DVTs, from the fully enrolled cohort of 75 patients. Subsequent to the VEITH presentation, two (2) of the DVTs were adjudicated by the SAVVE Clinical Events Committee (“CEC”) as being moderate and four (4) of the DVTs were adjudicated as being mild. In addition to the DVTs, the safety report also noted a higher-than-expected rate of pocket wound hematomas (anti-coagulation related bleeding outside of the target vein within the surgical cavity) within the first two (2) weeks after surgery, which were deemed to be moderate in severity by the CEC, as well as an expected rate of procedure related wound infections at the site of the skin incisions. The bleeds and wound infections were acute in nature and had no lasting negative impact on patient health or clinical outcomes.

On March 6, 2024, we released initial, six-month topline preliminary revised Venous Clinical Severity Score (rVCSS) efficacy data from the SAVVE study at the VENOUS2024 American Venous Forum Annual Meeting, in Tampa Florida. The data released at VENOUS 2024 indicated that,

overall, 97% of the study patients receiving the VenoValve showed clinical improvement as measured by rVCSS at six months, compared to baseline, with 74% of the study patients improving the three (3) or more rVCSS points needed to demonstrate VenoValve's clinical meaningful benefit (the "Clinical Meaningful Benefit"). The average improvement among the Clinical Meaningful Benefit cohort was 8 points, more than two and a half times the amount of rVCSS improvement required to demonstrate that the VenoValve provides Clinical Meaningful Benefit.

On April 24, 2024, follow-on preliminary rVCSS data was presented at the 46th Annual Charing Cross Symposium in London, England. At a weighted average subject follow-up of 11.64 months, the average improvement among the Clinical Meaningful Benefit (≥ 3 point rVCSS improvement) patient cohort was 8.46 points, including 9.29 points for patients at the two-year milestone, 8.08 points for patients at the one-year milestone, and 8.71 points for patients at the six-month milestone. All rVCSS evaluations were based on the patient's most recent clinical visit, compared to baseline. Overall, 94% of the study patients receiving the VenoValve showed clinical improvement as measured by rVCSS, at a weighted-average patient follow-up of 11.04 months for the clinical improvement cohort, and 72% of the study patients improved the three or more rVCSS points needed to demonstrate the VenoValve's Clinical Meaningful Benefit, at a weighted-average patient follow-up of 11.64 months for the Clinical Meaningful Benefit cohort. Total patient follow-up was 762 months for the clinical improvement cohort and 582 months for the Clinical Meaningful Benefit cohort.

On June 21, 2024, the Company presented data showing significant improvement for patients with venous ulcers enrolled in the SAVVE study at the Society for Vascular Surgery 2024 Vascular Annual Meeting in Chicago. The data presented included twenty-one venous ulcer patients who had reached their one-year milestone, representing thirty venous ulcers. Overall, 91% of venous ulcer patients evaluated at one year either had fully healed ulcers or ulcers that had improved. Of that group, 100% of venous ulcers with a duration of one year or less prior to VenoValve surgery were fully healed, with the majority (67%) fully healed 90 days after VenoValve surgery. For those with venous ulcers with a duration of more than one year prior to VenoValve surgery, 89% were either fully healed or improved at one year, representing a decrease in average of total ulcers of 85%. In addition, none of the patients with a fully healed venous ulcer had experienced an ulcer recurrence.

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 approval ("PMA") for the VenoValve, the Company expects 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. The enVVe system consists of the enVVe replacement venous valve, the enVVe delivery system, and the delivery system accessories. enVVe is designed to be 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 be poor candidates for a surgical device, and estimate the U.S. market for enVVe to be approximately 3.5 million patients.

Initial bench testing and acute pre-clinical testing for the enVVe valve were very successful. Adjustments to make it easier to load the enVVe valve into the enVVe delivery system are being finalized and the Company is currently manufacturing the necessary enVVe valves and enVVe delivery systems to begin a six-month chronic GLP study, which the Company expects to start in Q4 of 2024. The GLP study should be the final step necessary before filing for IDE approval to begin the enVVe pivotal study, which the Company expects to file in Q2 of 2025.

Capital

We finished 2023 with approximately $46.4 million of cash and investments and had approximately $39.1 million of cash and investments at June 30, 2024. Our future capital requirements will remain dependent upon a variety of factors, especially including the success of our clinical trials, related product development costs, and our ability to successfully bring products to market. We anticipate that our cash burn rate will increase from current levels of approximately $4 million to $5 million per quarter as we conduct our clinical trials and work toward bringing our product candidates to market.

Results of Operations

Comparison of the three months ended June 30, 2024 and 2023

Overview

We reported net losses of $5.0 million and $6.5 million for the three months ended June 30, 2024 and 2023, respectively, representing a decrease in net loss of $1.5 million, or 23.1%, resulting from a decrease in operating expenses and an increase in other income, as described in further detail below.

Revenues

As a developmental stage Company, our revenue, if any, is expected to be diminutive and dependent on our ability to commercialize our product candidates. We are not currently generating revenue and do not expect significant revenue until we successfully commercialize our lead product candidate.

Research and Development Expenses

For the three months ended June 30, 2024, research and development expenses decreased by $1.4 million or 33.3%, to $2.8 million from $4.2 million for the three months ended June 30, 2023. This decrease primarily resulted from $1.7 million in lower costs related the SAVVE study as the study was fully enrolled during 2023 resulting in the reduction of outreach and enrollment related activities and related costs, partially offset by a $0.3 million increase in personnel costs to support the SAVVE study and enVVe development.

Selling, General and Administrative Expenses

For the three months ended June 30, 2024, selling, general and administrative expenses were $2.6 million, flat from the three months ended June 30, 2023, which was also $2.6 million. This was due to the net effect of a $0.1 million decrease in share-based compensation, offset by a $0.1 million increase in legal costs.

Other Income

For the three months ended June 30, 2024, other income increased $0.1 million or 25.0% to $0.5 million from $0.4 million for the three months ended June 30, 2023. Other income in both periods reflects realized gains, interest, and unrealized gains from our program to invest excess cash in US Treasury bills.

Comparison of the six months ended June 30, 2024 and 2023

Overview

We reported net losses of $10.0 million and $12.9 million for the six months ended June 30, 2024 and 2023, respectively, representing a decrease in net loss of $2.9 million or 22.5%, due to a decrease in operating expenses of $2.6 million and an increase in other income of $0.3 million.

Research and Development Expenses

For the six months ended June 30, 2024, research and development expenses decreased by $1.9 million or 24.4%, to $5.9 million from $7.8 million for the six months ended June 30, 2023. This decrease resulted from $2.6 million in lower costs related the SAVVE study as it was fully enrolled during 2023 resulting in the elimination of costs related to enrolling patients in the study, partially offset by a $0.6 million increase in personnel costs due to increased payments to additional staff to support ENVVE product development and the SAVVE study, and $0.1 million in higher lab related costs.

Selling, General and Administrative Expenses

For the six months ended June 30, 2024, selling, general and administrative expenses decreased $0.7 million or 12.1%, to $5.1 million from $5.8 million for the six months ended June 30, 2023. Of this decrease, $0.9 million was due to share based compensation from grants made during 2021 because the expense related to portions of grants made during 2021 has been fully amortized and subsequent grants have been of lower value. This decrease in stock-based compensation expense was partially offset by a $0.2 million increase in legal costs.

Other (Income) Expense

For the six months ended June 30, 2024, other income increased $0.3 million to $1.0 million from $0.7 million for the six months ended June 30, 2023. Other income in both periods reflects realized gains, interest, and unrealized gains from our program to invest excess cash in U.S. bills.

Liquidity and Capital Resources

For the six-months ended June 30, 2024, the Company incurred a net loss of $9.9 million and used $7.5 million cash in operating activities. The net cash used in operating activities during the 2024 period decreased by $2.2 million from $9.7 million for the six months ended June 30, 2023.

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, and expects costs will increase, as the Company works to complete its clinical trials, enhance products, develop new products, expand its organization to bring those products to market, and operate as a public company. We are not currently generating revenue and do not expect significant revenue until we successfully commercialize one or more of our product candidates.

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 the SAVVE study, 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. We anticipate that our cash burn rate will increase from current levels of approximately $4 million to $5 million per quarter as we conduct our clinical trials and work toward bringing our product candidates to market.

We have historically funded our operations through financing activities and will need to raise additional capital in the future. Any inability to raise additional financing would have a material adverse effect on us.

Based on our cash and working capital as of June 30, 2024, we have sufficient capital resources to meet our obligations as they become due for at least one year after the date of this Quarterly Report and sustain operations.

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.

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 June 30, 2024, 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 June 30, 2024.

Changes in Internal Control over Financial Reporting

During the six months ended June 30, 2024, 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.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be subject to litigation and arbitration claims incidental to the Company's 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.

The Company and its Chief Executive Officer are parties to civil complaints 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. Originally filed as two separate complaints, Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857, they have now been consolidated and will be tried concurrently.

The complaints assert causes of action alleging constructive discharge in violation of public policy, failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement, retaliation under Labor Code Section 1102.5, unfair competition, defamation, and sex-based discrimination, and seeks damages for back pay, lost and unpaid wages, emotional and mental distress, consequential damages, punitive damages, compensatory damages and attorney's fees and costs.

The Company denies all claims in these matters, 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 these matters, which are currently set for trial on August 12, 2024.

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 February 29, 2024.

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.

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 and not filed herewith.

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: July 31, 2024

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 Financial 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

   (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.

July 31, 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;

   (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.

July 31, 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 June 30, 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.

/s/ Robert Berman
Robert Berman
Chief Executive Officer and Principal Executive Officer

Dated: July 31, 2024

/s/ Craig Glynn
Craig Glynn
Chief Financial Officer and Principal Financial Officer

Dated: July 31, 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.