

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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 PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission File Number: 001-38389

Motus GI Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

1301 East Broward Boulevard, 3rd Floor
Ft. Lauderdale, FL

(Address of principal executive offices)

81-4042793

(I.R.S. Employer
Identification Number)

33301

(Zip code)

(954) 541 8000

(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchanged on Which Registered
Common Stock, \$0.0001 par value per share	MOTS	The Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 3, 2023, 578,515 shares of the registrant's common stock, \$0.0001 par value, were issued and outstanding.

Motus GI Holdings, Inc. and Subsidiaries
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PART I — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Motus GI Holdings, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,724	\$ 14,042
Accounts receivable	102	59
Inventory, current	407	488
Prepaid expenses and other current assets	509	781
Total current assets	<u>6,742</u>	<u>15,370</u>
Fixed assets, net	1,101	1,325
Inventory, non-current	374	511
Right-of-use assets	261	428
Other non-current assets	13	13
Total assets	<u>\$ 8,491</u>	<u>\$ 17,647</u>
Liabilities and Shareholders' (Deficiency) Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,466	\$ 1,969
Operating lease liabilities - current	220	245
Other current liabilities	62	53
Current portion of long-term debt, net of unamortized debt discount of \$132 and \$182, respectively	2,781	2,532
Total current liabilities	<u>4,529</u>	<u>4,799</u>
Contingent royalty obligation	-	1,212
Operating lease liabilities - non-current	34	178
Convertible note, net of unamortized debt discount of \$64 and \$108, respectively	3,936	3,892
Long-term debt, net of unamortized debt discount of \$44 and \$135, respectively	2,470	4,589
Total liabilities	<u>10,969</u>	<u>14,670</u>
Commitments and contingent liabilities (Note 9)		
Shareholders' (deficiency) equity		
Common stock \$0.0001 par value; 115,000,000 shares authorized; 530,449 and 310,494 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	-	-
Additional paid-in capital	148,935	144,328
Accumulated deficit	(151,413)	(141,351)
Total shareholders' (deficiency) equity	<u>(2,478)</u>	<u>2,977</u>
Total liabilities and shareholders' (deficiency) equity	<u>\$ 8,491</u>	<u>\$ 17,647</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.
(Reflects the retrospective application of the 1-for-15 reverse stock split effective November 2, 2023, see Note 3)

Motus GI Holdings, Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Loss
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ 86	\$ 278	\$ 255	\$ 483
Operating expenses:				
Cost of revenue - sales	22	83	62	166
Cost of revenue - impairment of inventory	26	-	221	159
Research and development	693	1,573	2,906	4,261
Sales and marketing	188	1,349	1,367	3,554
General and administrative	1,551	1,978	5,134	6,167
Total costs and expenses	<u>2,480</u>	<u>4,983</u>	<u>9,690</u>	<u>14,307</u>
Loss from Operations	(2,394)	(4,705)	(9,435)	(13,824)
Gain (loss) on change in estimated fair value of contingent royalty obligation	(53)	34	103	(29)
Finance expense, net	(222)	(310)	(707)	(1,001)
Foreign currency gain (loss)	(10)	17	(23)	(61)
Net loss	<u>\$ (2,679)</u>	<u>\$ (4,964)</u>	<u>\$ (10,062)</u>	<u>\$ (14,915)</u>
Basic and diluted loss per common share:	<u>\$ (4.28)</u>	<u>\$ (26.99)</u>	<u>\$ (20.80)</u>	<u>\$ (80.97)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>626,470</u>	<u>183,897</u>	<u>483,711</u>	<u>184,210</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.
(Reflects the retrospective application of the 1-for-15 reverse stock split effective November 2, 2023, see Note 3)

Motus GI Holdings, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Shareholders' (Deficiency) Equity
(unaudited, in thousands, except share and per share amounts)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total shareholders' (deficiency) equity
	Shares	Amount			
Balance at January 1, 2023	310,494	\$ -	\$ 144,328	\$ (141,351)	\$ 2,977
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of \$ 19	7,942	-	102	-	102
Share-based compensation	-	-	222	-	222
Net loss	-	-	-	(4,386)	(4,386)
Balance at March 31, 2023	318,436	\$ -	\$ 144,652	\$ (145,737)	\$ (1,085)
Private placement offering, net of financing fees of \$731	35,000	-	3,070	-	3,070
Issuance of common shares upon vesting of restricted stock units	104	-	-	-	-
Share-based compensation	-	-	49	-	49
Net loss	-	-	-	(2,997)	(2,997)
Balance at June 30, 2023	353,540	\$ -	\$ 147,771	\$ (148,734)	\$ (963)
Issuance of common shares upon exercise of warrants	79,867	-	-	-	-
Issuance of common shares upon extinguishment of contingent royalty obligation, net of issuance fees of \$38	97,042	-	1,071	-	1,071
Share-based compensation	-	-	93	-	93
Net loss	-	-	-	(2,679)	(2,679)
Balance at September 30, 2023	530,449	\$ -	\$ 148,935	\$ (151,413)	\$ (2,478)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Shares	Amount			
Balance at January 1, 2022	160,915	\$ -	\$ 132,411	\$ (122,754)	\$ 9,657
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of \$111	19,917	-	3,004	-	3,004
Issuance of common shares upon vesting of restricted stock units	914	-	-	-	-
Issuance of common stock for board of directors' compensation	1,630	-	235	-	235
Share-based compensation	-	-	521	-	521
Net loss	-	-	-	(4,811)	(4,811)
Balance at March 31, 2022	183,376	\$ -	\$ 136,171	\$ (127,565)	\$ 8,606
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of \$6	541	-	45	-	45
Issuance of common shares upon vesting of restricted stock units	278	-	-	-	-
Share-based compensation	-	-	461	-	461
Net loss	-	-	-	(5,140)	(5,140)
Balance at June 30, 2022	184,195	\$ -	\$ 136,677	\$ (132,705)	\$ 3,972
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of \$55	17,208	-	1,324	-	1,324
Issuance of common shares upon vesting of restricted stock units	277	-	-	-	-
Fractional shares settled in cash pursuant to reverse stock split	(136)	-	(11)	-	(11)
Share-based compensation	-	-	441	-	441
Net loss	-	-	-	(4,964)	(4,964)
Balance at September 30, 2022	201,544	\$ -	\$ 138,431	\$ (137,669)	\$ 762

The accompanying notes are an integral part of these condensed consolidated financial statements.
(Reflects the retrospective application of the 1-for-15 reverse stock split effective November 2, 2023, see Note 3)

Motus GI Holdings, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	For the Nine Months Ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (10,062)	\$ (14,915)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	341	381
Amortization of debt issuance costs	184	195
(Gain) loss on change in estimated fair value of contingent royalty obligation	(103)	29
Share- based compensation	364	1,423
Issuance of common stock for board of directors' compensation	-	177
Impairment of inventory	221	159
Impairment of fixed assets	-	46
Amortization on operating lease right-of-use asset	176	253
Loss on lease termination	11	
Changes in operating assets and liabilities:		
Accounts receivable	(43)	(52)
Inventory	(16)	(843)
Prepaid expenses and other current assets	266	(167)
Accounts payable and accrued expenses	(503)	79
Operating lease liabilities - current and non-current	(183)	(255)
Other current liabilities	9	61
Net cash used in operating activities	(9,338)	(13,429)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(104)	(215)
Net cash used in investing activities	(104)	(215)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common shares	121	4,544
Fractional shares paid in cash pursuant to reverse stock split	-	(11)
Repayment of term debt	(2,010)	-
Gross proceeds from private placement offering	3,537	-
Equity financing fees	(524)	(158)
Net cash provided by financing activities	1,124	4,375
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,318)	(9,269)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	14,042	22,563
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 5,724	\$ 13,294
SUPPLEMENTAL CASH FLOW INFORMATION:		
CASH PAID FOR:		
Interest	\$ 690	\$ 779
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Common stock issued for prepaid board of directors' compensation	\$ -	\$ 58
Reclassification of inventory to fixed assets	\$ 13	\$ 163
Reclassification of prepaid expenses to fixed assets	\$ -	\$ 4
Purchase of fixed assets in accounts payable and accrued expenses	\$ -	\$ 12
Financing costs included in accounts payable and accrued expenses	\$ 38	\$ 13
Extinguishment of contingent royalty obligation	\$ 1,109	\$ -
Operating lease liabilities arising from obtaining right-of-use assets	\$ -	\$ 3
Non-cash issuance costs from private placement	\$ 264	\$ -
Right-of-use asset obtained in exchange for lease obligation	\$ 69	\$ -

The accompanying notes are an integral part of these condensed consolidated financial statements.
(Reflects the retrospective application of the 1-for-15 reverse stock split effective November 2, 2023, see Note 3)

Motus GI Holdings, Inc. and Subsidiaries
Notes to the Interim Condensed Consolidated Financial Statements
(unaudited, in thousands, except share and per share amounts)

Note 1 – Description of Business

Motus GI Holdings, Inc. (the “Company”) was incorporated in Delaware, U.S.A. in September 2016. The Company and its subsidiaries, Motus GI Technologies, Ltd. and Motus GI, LLC, are collectively referred to as “Motus GI” or the “Company”.

The Company has developed the Pure-Vu System, a medical device that has been cleared by the U.S. Food and Drug Administration (the “FDA”) to help facilitate the cleansing of a poorly prepared gastrointestinal tract during colonoscopy and to help facilitate upper gastrointestinal (“GI”) endoscopy procedures. The Pure-Vu System has received a CE Mark in the EU for use in colonoscopy. The Pure-Vu System integrates with standard and slim colonoscopes, as well as gastrosopes, to improve visualization during colonoscopy and upper GI procedures while preserving established procedural workflow and techniques. Through irrigation and evacuation of debris, the Pure-Vu System is designed to provide better-quality exams. The Company received 510(k) clearance in October 2023 from the FDA for the Pure-Vu EVS System for use in the Upper GI tract and Gen 4 Colon and will commence market introduction of this product in the coming months. Both devices leverage the same Workstation and feature key enhancements such as a larger and more powerful suction channel, more efficient irrigation jets, a smaller profile distal tip that offers enhanced flexibility during insertion, enhanced navigation and a much easier bed side set up. The Company does not expect to generate significant revenue from product sales until it further expands its commercialization efforts, which is subject to significant uncertainty.

Note 2 – Basis of Presentation and Going Concern Uncertainty

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the 2022 10-K filed with the SEC on March 31, 2023. The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information, the instructions for Form 10-Q and the rules and regulations of the SEC. Accordingly, since they are interim statements, the accompanying condensed consolidated financial statements do not include all of the information and notes required by GAAP for annual financial statements, but reflect all adjustments consisting of normal, recurring adjustments, that are necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of the results that may be expected for any future periods. The December 31, 2022 condensed consolidated balance sheet information was derived from the audited financial statements as of that date.

The Company has generated limited revenues to date from the sale of products. The Company has never been profitable and has incurred significant net losses each year since its inception, including a loss of \$10.1 million for the nine months ended September 30, 2023. The Company expects to continue to incur net operating losses for the foreseeable future. Net cash used in operating activities for the nine months ended September 30, 2023 was \$9.3 million. As of September 30, 2023, the Company had cash and cash equivalents of \$5.7 million and an accumulated deficit of \$151.4 million.

In January and April 2023, the Company committed to a restructuring initiative designed to position the Company to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. If a strategic transaction is not completed, or if additional financing is not available, the Company may not be able to service our outstanding indebtedness and our payables and may have to file for bankruptcy protection or pursue a dissolution of the Company and liquidation of all of the Company’s remaining assets. In such an event, the amount of cash available for distribution to the Company’s shareholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as the Company continues to fund its operations and service the Company’s outstanding indebtedness. The Company cannot provide assurance as to the amount of cash that will be available to distribute to shareholders, if any, after paying its debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution, if any. Such conditions raise substantial doubt about the Company’s ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that may result from this uncertainty.

The Company has financed its operations primarily through sales of equity-related securities and debt. In March 2021, we entered into an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Oppenheimer & Co. Inc. (“Oppenheimer”), under which we may offer and sell from time to time common shares having an aggregate offering price of up to \$25.0 million. During the nine months ended September 30, 2023, the Company sold approximately 7,942 shares of our common stock under this agreement, resulting in net cash proceeds of \$102 thousand, after deducting issuance costs of \$19 thousand.

On May 17, 2023, the Company entered into a securities purchase agreement with an accredited investor pursuant to which it agreed to issue and sell in a private placement an aggregate of (i) 35,000 shares of common stock, (ii) warrants to purchase up to 241,134 shares of common stock (the “Pre-Funded Warrants”) and (iii) warrants to purchase up to 276,134 shares of common stock (the “Common Warrants”). The purchase price was \$12.675 for each share of common stock and \$12.6735 for each Pre-Funded Warrant, resulting in net proceeds of approximately \$3.0 million, inclusive of issuance costs of \$0.5 million and exclusive of warrant issuance costs of \$0.2 million. See Note 11 for further discussion of the Private Placement.

Note 3 – Summary of Significant Accounting Policies

Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the nine months ended September 30, 2023 are consistent with those discussed in Note 3 to the consolidated financial statements in the Company’s 2022 Annual Report on Form 10-K. There have been no material changes to the Company’s significant accounting policies during the nine months ended September 30, 2023.

Reverse Stock Split

On November 2, 2023, the Company effected a reverse stock split of its issued and outstanding common stock, par value \$0.0001 per share, at a ratio of 1-for-15 (the “2023 Reverse Stock Split”). Shares of common stock underlying outstanding stock options and other equity instruments convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

No fractional shares were issued in connection with the 2023 Reverse Stock Split. Stockholders who would otherwise be entitled to a fractional share of common stock instead receive a proportional cash payment.

All of the Company’s historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these condensed consolidated financial statements have been adjusted, on a retroactive basis, to reflect the 2023 Reverse Stock Split.

Basis of presentation and principles of consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP and include the accounts of the Company and its wholly owned subsidiaries, Motus Ltd., an Israel corporation, which has operations in Tirat Carmel, Israel, and Motus Inc., a Delaware corporation, which has operations in the U.S. All inter-company accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Basic and diluted net loss per share

Basic net loss per share is calculated by dividing the net loss attributable to common shareholders by the weighted average number of common shares outstanding during the applicable period. Diluted net loss per share is calculated by dividing the net loss attributable to common shareholders by the weighted average number of common shares outstanding for the applicable period, including any potentially dilutive securities such as stock options, unvested restricted stock, warrants, and other convertible instruments unless the result of inclusion would be antidilutive. The dilutive effect of restricted stock units subject to vesting and other share-based payment awards is calculated using the "treasury stock method," which assumes that the "proceeds" from the exercise of these instruments are used to purchase common shares at the average market price for the period. The dilutive effect of convertible securities is calculated using the "if-converted method." Under the if-converted method, securities are assumed to be converted at the beginning of the period, and the resulting common shares are included in the denominator of the diluted calculation for the entire period being presented. The Company's net loss is net loss attributable to common shareholders for all periods presented. The Company would use the two-class method to compute net income per common share, as it issued securities, other than common stock, that contractually entitle the holders to participate in dividends and earnings. No such adjustment to earnings is made during periods with a net loss, as the holders of the participating securities have no obligation to fund losses. The two-class method presentation will only be required if and when the Company reports net income.

Given the nominal exercise price of the Company's issuance of Pre-Funded Warrants, such Pre-Funded Warrants are included in the calculation of basic and diluted net loss per share as the exercise price per warrant is deemed nonsubstantive when compared to the fair value of the underlying common shares. The 161,266 unexercised pre-funded warrants as of September 30, 2023 were included in the Company's calculation of basic and diluted loss per share.

The Company's Convertible Note, on an as converted basis into common stock of 9,523 shares, and the following outstanding stock-based awards and warrants, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect due to net loss for the periods:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Outstanding options	62,589	26,642	62,589	26,642
Unvested restricted stock units	1,079	1,630	1,079	1,630
Warrants	312,143	26,238	312,143	26,238
Total	<u>375,811</u>	<u>54,510</u>	<u>375,811</u>	<u>54,510</u>

Income taxes

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of September 30, 2023 and December 31, 2022, the Company had a full valuation allowance against its deferred tax assets.

For the three and nine months ended September 30, 2023 and 2022, the Company recorded zero income tax expense. No tax benefit has been recorded in relation to the pre-tax loss for the three and nine months ended September 30, 2023 and 2022, due to a full valuation allowance to offset any deferred tax asset related to net operating loss carry forwards attributable to the losses.

Accounting Pronouncements- Adopted

In September 2016, the FASB issued ASU 2016-13, “Financial Instruments – Credit Losses” to improve information on credit losses for financial assets and net investment in leases that are not accounted for at fair value through net income. ASU 2016-13 replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses. In April 2019 and May 2019, the FASB issued ASU No. 2019-04, “Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments” and ASU No. 2019-05, “Financial Instruments-Credit Losses (Topic 326): Targeted Transition Relief” which provided additional implementation guidance on the previously issued ASU. In November 2019, the FASB issued ASU 2019-10, “Financial Instruments - Credit Loss (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842),” which defers the effective date for public filers that are considered smaller reporting companies as defined by the Securities and Exchange Commission to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted this ASU on January 1, 2023. The adoption of this ASU did not result in a material impact to the consolidated financial statements and disclosures.

Accounting Pronouncements- Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This guidance simplifies the accounting for convertible instruments primarily by eliminating the existing cash conversion and beneficial conversion models within Subtopic 470-20, which will result in fewer embedded conversion options being accounted for separately from the debt host. The guidance also amends and simplifies the calculation of earnings per share relating to convertible instruments. This guidance is effective for annual periods beginning after December 15, 2021, including interim periods within that reporting period, excluding smaller reporting companies. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within that reporting period, using either a full or modified retrospective approach. Since the Company is a smaller reporting company (“SRC”), implementation is not needed until after December 15, 2023. We are currently evaluating the impact of the provisions of this guidance on our condensed consolidated financial statements.

Note 4 –Fair Value Measurements

Liabilities measured and recorded at fair value on a recurring basis consisted of the following at September 30, 2023 and December 31, 2022:

	September 30, 2023			
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Contingent royalty obligation	\$ -	\$ -	\$ -	\$ -
December 31, 2022				
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Contingent royalty obligation	\$ -	\$ -	\$ 1,212	\$ 1,212

Financial instruments with carrying values approximating fair value include cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, and certain other current liabilities, due to their short-term nature. Debt instruments are measured at amortized cost on the Company’s consolidated balance sheets. If measured at fair value in the financial statements, these instruments would be classified as Level 2 in the fair value hierarchy.

In estimating the fair value of the Company's contingent royalty obligation, the Company used the discounted cash flow method as of September 12, 2023 and December 31, 2022. Based on the fair value hierarchy, the Company classified contingent royalty obligation within Level 3 because valuation inputs are based on projected revenues discounted to a present value. The contingent royalty obligation is re-measured at each balance sheet date and at September 12, 2023 using several assumptions, including the following: 1) estimated sales growth, 2) length of product cycle, 3) patent life, 4) discount rate (28.5% and 23% as of September 12, 2023 and December 31, 2022, respectively), and 5) rate of royalty payment (3% as of September 12, 2023 and December 31, 2022).

As noted in Note 9, under the Amendment Agreement, the Company extinguished its royalty obligation in exchange for equity interests. The Company measured the difference between the fair value of the shares of common stock issued and the carrying value (at a final fair value) of the royalty obligation as a gain. As the holder of a majority of the Royalty Payment Rights Certificates is considered a related party, as noted in Note 10, the Company recorded the retirement of the royalty obligation based on the total value of shares issued as well as the gain on settlement within equity as additional paid in capital as a capital transaction.

Note 5 – Inventory

Inventory is stated at lower of cost or net realizable value using the weighted average cost method and is evaluated at least annually for impairment. Write-downs for potentially obsolete or excess inventory are made based on management's analysis of inventory levels, historical obsolescence and future sales forecasts. For the three and nine months ended September 30, 2023, an inventory impairment of \$26 and \$221, respectively, and for the three and nine months ended September 30, 2022, an inventory impairment of \$0 and \$159, respectively, was recorded. Inventories that exceed estimated realization for the next twelve months from balance sheet date based on future sales forecasts are classified as long-term assets.

Inventory at September 30, 2023 and December 31, 2022 consisted of the following:

	September 30, 2023	December 31, 2022
Raw materials	\$ 554	\$ 697
Work-in-process	177	155
Finished goods	672	548
Inventory reserve	(622)	(401)
Inventory, net	\$ 781	\$ 999
Inventory, current	\$ 407	\$ 488
Inventory, non-current	\$ 374	\$ 511

Note 6 – Fixed assets, net

Fixed assets, summarized by major category, consist of the following for the years ended:

	September 30, 2023	December 31, 2022
Office equipment	\$ 171	\$ 171
Computers and software	321	321
Machinery	1,154	1,049
Lab and medical equipment	1,489	1,477
Leasehold improvements	200	200
Total	3,335	3,218
Less: accumulated depreciation and amortization	(2,234)	(1,893)
Fixed assets, net	\$ 1,101	\$ 1,325

Depreciation and amortization expense for the three and nine months ended September 30, 2023 was \$111 and \$341, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2022 was \$128 and \$381, respectively. The Company incurred a loss on the impairment of fixed assets in the amount of \$10 and \$46 for the three and nine months ended September 30, 2022.

Note 7 – Leases

The Company leases offices in Fort Lauderdale, Florida and Israel which expire in November 2024 and December 2023, respectively. The Company also leases vehicles under operating leases that expire at various dates through 2025.

The components of lease cost and supplemental balance sheet information for the Company's lease portfolio were as follows:

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
Lease Cost				
Operating lease (income) cost, net of related party license fee	\$ (36)	\$ 16	\$ (18)	\$ 78
Variable lease cost	103	30	167	90
Total lease cost	\$ 67	\$ 46	\$ 149	\$ 168
			As of September 30, 2023	As of December 31, 2022
Assets				
Operating lease, right-of-use-asset			\$ 261	\$ 428
Liabilities				
Current				
Operating lease liabilities			\$ 220	\$ 245
Non-current				
Operating lease liabilities, net of current portion			34	178
Total lease liabilities			\$ 254	\$ 423
Other information:				
Weighted average remaining lease term - operating leases			1.36 years	1.79 years
Weighted-average discount rate - operating leases			7.33%	7.36%

The Company's lease expense is included in general and administrative expenses which is net of related party license fee of \$67 and \$66 for the three months ended September 30, 2023 and 2022, and \$202 and \$173 for the nine months ended September 30, 2023 and 2022.

Note 8 – Convertible Note and Long-Term Debt

On July 16, 2021 (the "Effective Date"), the Company entered into a loan facility (the "Kreos Loan Agreement") with Kreos Capital VI (Expert Fund) LP (the "Lender"). Under the Kreos Loan Agreement, the Lender will provide the Company with access to term loans in an aggregate principal amount of up to \$12,000 (the "Loan") in three tranches as follows: (a) on the Effective Date, a loan in the aggregate principal amount of \$4,000 (the "Convertible Note", or "Tranche A"), (b) on the Effective Date, a loan in the aggregate principal amount of \$5,000 ("Tranche B"), and (c) available until December 31, 2021, a loan in the aggregate principal amount of \$3,000 ("Tranche C", together with Tranche B, the "Long-term Debt"). The Kreos Loan Agreement contains customary representations and warranties, indemnification provisions in favor of the Lender, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. Outstanding borrowings under the Loan are secured by a first priority security interest on substantially all of the personal property assets of the Company, including the Company's material intellectual property and equity interests in its subsidiaries. There are no liquidity or financial covenants.

The Convertible Note and Tranche B were funded on the Effective Date. As of December 31, 2021, the Company drew down the full \$3,000 aggregate principal amount of Tranche C.

The Convertible Note requires forty-eight monthly interest only payments at 7.75% per annum commencing after the Effective Date and thereafter full payment of the then outstanding principal balance of the Convertible Note on July 1, 2025. The Kreos Loan Agreement contains features that would permit the Lender to convert all or any portion of the outstanding principal balance of the Convertible Note at any time, pursuant to which the converted part of the Convertible Note will be converted into that number of shares of common stock of the Company to be issued to the Lender at a price per share equal to the conversion price, of \$420 per share. Following the conversion of any portion of the outstanding principal balance of the Convertible Note, the principal balance of the Convertible Note remaining outstanding shall continue to bear interest at 7.75% per annum. The Tranche B loan requires interest only monthly payments commencing on the Effective Date until September 30, 2022 and, thereafter, thirty-three monthly payments of principal and interest accrued thereon until June 1, 2025. The Tranche C loan requires interest only monthly payments commencing on the date of the draw down until September 30, 2022 and, thereafter, thirty-two monthly payments of principal and interest accrued thereon until June 1, 2025.

In connection with the Kreos Loan Agreement, the Company also issued to the Lender a warrant ("Warrant"), dated July 16, 2021, to purchase up to 636 shares of the Company's common stock, at an exercise price of \$314.22 per share, payable in cash or on a cashless basis according to the formula set forth in the Warrant. The exercise price of the Warrant and the number of shares issuable upon exercise of the Warrant are subject to adjustments for stock splits, combinations, stock dividends or similar events. The Warrant is exercisable until the date that is ten years after the date of issuance. The Company concluded that the Warrant is indexed to its own stock and accordingly is classified as equity.

The Company treated Tranche A, Tranche B and Tranche C, and the Warrant as three separate freestanding financial instruments with the proceeds received in connection with the transaction allocated amongst the instruments based on relative fair value. The proceeds received in connection with the transaction allocated amongst the instruments based on relative fair value resulted in \$165 being allocated to the Warrant and a corresponding amount recorded as a debt discount to the Convertible Note and Long-term Debt. The Company recorded an aggregate debt discount of \$845 related to the Loan, inclusive of the debt discount of \$165 in connection to the Warrant, which will be amortized to interest expense over the term of each respective tranche using the effective interest method. The Company also paid \$540 in cash for debt issuance costs. Additionally, per the Kreos Loan Agreement, with respect to the Long-term Debt, there is an advance payment of \$274 that is recorded at a debt discount. The advance payment represents the last month's payment in relation to the Long-term Debt. There is also an end of loan payment of \$140 which is included on the balance sheet as a liability within the Long-term Debt and also within the total aggregate debt discount of \$845.

For the nine months ended September 30, 2023, interest expense for the Loan was as follows:

Contractual interest expense	\$	690
Amortization of debt issuance costs		184
Total interest expense	\$	<u>874</u>

For the three months ended September 30, 2023, interest expense for the Loan was as follows:

Contractual interest expense	\$	220
Amortization of debt issuance costs		61
Total interest expense	\$	<u>281</u>

Future principal payments under the Convertible Note as of September 30, 2023 are as follows:

Years Ending December 31,	Amount
2023 (remaining 3 months)	\$ -
2024	-
2025	4,000
Total future principal payments	4,000
Less unamortized debt issuance costs	64
Total balance	<u>\$ 3,936</u>

Future principal payments under the Long-term Debt as of September 30, 2023 are as follows:

Years Ending December 31,	Amount
2023 (remaining 3 months)	\$ 703
2024	2,983
2025	1,601
Total future principal payments	5,287
End of loan payments	140
Less unamortized debt issuance costs of current portion of long-term debt	(132)
Less unamortized debt issuance costs of non-current portion of long-term debt	(44)
Total balance	\$ 5,252
Less long-term debt, current	\$ 2,781
Long-term debt, net of current portion	\$ 2,470

Note 9 – Commitments and Contingencies

The Company has entered into and expects to enter into from time to time in the future, license agreements, strategic alliance agreements, assignment agreements, research service agreements, and similar agreements related to the advancement of its research and development efforts. Significant agreements are described in detail in the Company's 2022 Form 10-K. While specific amounts will differ from quarter to quarter, the Company believes its overall activities regarding these agreements are materially consistent with those described in the 2022 Form 10-K. In addition to the specific agreements described in the 2022 Form 10-K, the Company has entered into, and will in the future enter into, other research and service provider agreements for the advancement of its research and development efforts. The Company expects to pay additional amounts in future periods in connection with existing and future research and service provider agreements.

Royalty Payment Rights on Royalty Payment Rights Certificates

The Company issued certain (i) Royalty Payment Rights Certificates, as amended ("Royalty Payment Rights Certificates") to the former holders of the Company's shares of Series A Convertible Preferred Stock, par value \$0.0001 per share (the "Series A Convertible Preferred Stock" and such holders, the "Certificate Holders"), with the right to receive certain single digit royalties for the achievement of certain commercialization milestones (the "Royalty Amount"), and (ii) Placement Agent Royalty Payment Rights Certificates dated December 22, 2016 (the "Placement Agent Payment Rights Certificates") to Aegis Capital Corp., a New York corporation (the "Placement Agent") or its designees, with the right to receive a payment equal to a percentage of the aggregate Royalty Amount paid to the Certificate Holders (the "Certificate Payment").

On September 12, 2023 (the "Effective Date"), the Company, entered into an Amendment Agreement (the "Amendment Agreement") with the holders of a majority of the Royalty Payment Rights Certificates to cancel the rights of all Certificate Holders to receive the Royalty Amounts in exchange for an aggregate of 88,221 shares of the Company's common stock (the "Certificate Holder Securities"). As a result, the right of the holders of the Placement Agent Payment Rights Certificates to receive the Certificate Payment was also cancelled, in exchange for an aggregate of 8,821 shares (such shares, together with the Certificate Holder Securities, the "Exchange Securities"). As such, effective September 12, 2023, the Company agreed to issue a total of 97,042 shares of the Company's common stock to settle all outstanding royalty payment obligations.

The Company measured the difference between the fair value of the shares of common stock issued and the carrying value (at a final fair value) of the royalty obligation as a gain. As the holder of a majority of the Royalty Payment Rights Certificates is considered a related party, as noted in Note 10, the Company recorded the extinguishment of the royalty obligation based on the total fair value of shares issued as well as the gain on settlement within equity as additional paid in capital as a capital transaction.

	Extinguishment of Royalty Obligation
Balance at December 31, 2022	\$ 1,212
Change in estimated fair value of royalty obligation	(103)
Balance at September 12, 2023	1,109
Less fair value of common stock exchanged for extinguishment of royalty obligation	711
Gain on extinguishment – recorded within additional paid-in-capital	\$ 398

Note 10 – Related Party Transactions

Shared Space Agreement

In January 2020, the Company entered into a license agreement (the “Shared Space Agreement”) with Orchestra BioMed, Inc. (OBIO), a greater than 5% holder of the Company’s common stock and entity. Pursuant to the Shared Space Agreement, the Company granted a license to OBIO for the use of portions of the office space not being used by the Company in the Company’s leased facility in Fort Lauderdale, Florida (the “Premises”), and a proportionate share of common areas of such Premises, which previously covered approximately 35% of the Premises and was to expand incrementally to approximately 60 to 70% of the Premises by September 2024. In May 2022, the Company entered into an amendment to the Shared Space Agreement. Pursuant to the amendment, the area covered by the Shared Space Agreement was expanded to 95% of the premises and the aggregate license fees will generally range from approximately \$212 to approximately \$270 in any given calendar year during the term of the Shared Space Agreement until the termination of the lease in November 2024. During the three and nine months ended September 30, 2023, the Company recorded a license fee of \$67 and \$202 in relation to the Shared Space Agreement. During the three and nine months ended September 30, 2022, the Company recorded a license fee of \$66 and \$173, respectively, in relation to the Shared Space Agreement. This amount is netted with rent expense in general and administrative expenses.

Extinguishment of Royalty Obligation

As noted in Note 9, under the Amendment Agreement, the Company extinguished its royalty obligation in exchange for equity interests. OBIO held the majority of the Royalty Payment Rights Certificates, and as such approved the Amendment Agreement and the settlement exchange. OBIO received 46,768 shares as a part of the settlement of all outstanding royalty payment obligations.

Note 11 – Share-based compensation

The following table sets forth total non-cash share-based compensation for the issuance of common stock, options to purchase common stock, warrants to purchase common stock, and restricted stock unit awards by operating statement classification for the three and nine months ended September 30, 2023 and 2022:

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 27	\$ 96	\$ 107	\$ 292
Sales and marketing	5	60	6	184
General and administrative	61	285	251	947
Total	\$ 93	\$ 441	\$ 364	\$ 1,423

As of September 30, 2023, unamortized share-based compensation for stock options was \$468, with a weighted-average recognition period of 1.20 years.

Stock option and warrant activity

A summary of the Company’s stock option and warrant activity is as follows:

	Options		Warrants	
	Shares Underlying Options	Weighted Average Exercise Price	Shares Underlying Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2022	26,567	\$ 640.51	26,088	\$ 759.26
Granted	45,712	\$ 8.99	*531,074	\$ 6.03
Exercised	-	\$ -	(79,866)	\$ -
Expired	(6,311)	\$ 662.79	(3,888)	\$ 1,587.38
Forfeited	(3,380)	\$ 202.16	-	\$ -
Outstanding at September 30, 2023	62,588	\$ 200.79	473,408	\$ 9.16
Exercisable at September 30, 2023	15,551	\$ 764.46	473,408	\$ 9.16

* Includes 241,134 prefunded warrants at an exercise price of \$0.0001 per share

As of September 30, 2023, there were 563 nonvested restricted stock unit awards at a weighted average grant date fair value of \$80.63. As of December 31, 2022, there were 1,346 nonvested restricted stock unit awards at a weighted average grant date fair value of \$277.57.

As of September 30, 2023, unamortized stock compensation for restricted stock units was \$36, with a weighted-average recognition period of 0.60 years.

Issuance of Warrants to Purchase Common Stock

In February 2020, the Company entered into a services agreement whereby it agreed to issue warrants to purchase 400 shares of common stock of the Company. The warrants fully vested over a one-year period on a monthly basis and expire three years from the date of issuance and were exercisable at weighted average exercise price equal to \$849.00 per share of common stock. In March 2022, the Company granted new warrants as a replacement to the vested warrants held by the service provider, for which all the share-based compensation expense had been recognized in prior fiscal periods. The issuance of new warrants concurrently with the cancellation of the existing warrants was treated as a modification. The Company agreed to issue replacement warrants to purchase 400 shares of common stock of the Company exercisable at a price equal to \$150 per share of common stock. The replacement warrants immediately vested upon issuance and expire three years from the date of issuance. As a result, the Company recognized \$0 and \$26 of share-based compensation for the nine months ended September 30, 2023 and 2022 respectively, related to the incremental fair value which is equal to the excess of the fair value of the new stock options granted over the fair value of the original award on the cancellation date.

Private Placement Offering

On May 17, 2023, the Company entered into a securities purchase agreement with an accredited investor pursuant to which it agreed to issue and sell in a private placement an aggregate of (i) 35,000 shares of common stock, (ii) warrants to purchase up to 241,134 shares of common stock (the “Pre-Funded Warrants”) and (iii) warrants to purchase up to 276,134 shares of common stock (the “Common Warrants”). The purchase price was \$12.675 for each share of common stock and \$12.674 for each Pre-Funded Warrant, resulting in net proceeds of approximately \$3.0 million, inclusive of issuance costs of \$0.5 million and exclusive of warrant issuance costs of \$0.2 million. The closing of the offering occurred on May 19, 2023. Each Common Warrant is exercisable for a period of five and one-half years from the issuance date at an exercise price of \$10.80 per share, subject to adjustment, and may, under certain circumstances, be exercised on a cashless basis. Each Pre-Funded Warrant is exercisable until exercised in full at an exercise price of \$0.0001 per share and may be exercised on a cashless basis.

The measurement of fair value of the Pre-Funded Warrants was determined utilizing a Black-Scholes model. The relative fair value of these Pre-Funded Warrants was estimated to be \$1.7 million on May 19, 2023, and is reflected within additional paid-in capital as of September 30, 2023 as the Pre-Funded Warrants were determined to be equity classified.

The measurement of fair value of the Common Warrants was determined utilizing a Black-Scholes model. The relative fair value of these Common Stock Warrants was estimated to be \$1.5 million on May 19, 2023 and is reflected within additional paid-in capital as of September 30, 2023, as the Common Stock Warrants were determined to be equity classified.

In addition, pursuant to the terms of the offering, the Company issued the placement agent, H.C. Wainwright & Co., LLC., warrants to purchase up to 13,806 shares of the Company’s common stock (the “Placement Agent Warrants”). The Placement Agent Warrants are exercisable for a period of five and one-half years from the issuance date, at an exercise price of \$15.845 per share, subject to adjustment, and may, under certain circumstances, be exercised on a cashless basis. As these Placement Agent Warrants were issued for services provided in facilitating the private placement, the Company recorded the fair value of such Placement Agent Warrants as a cost of capital on the issuance date. The measurement of fair value was determined utilizing a Black-Scholes model. The relative fair value of these Placement Agent Warrants was estimated to be \$0.1 million on May 19, 2023, and is reflected within additional paid-in capital as of September 30, 2023 as the Placement Agent Warrants were determined to be equity classified.

As of November 13, 2023, Pre-Funded Warrants for 241,134 shares of common stock were exercised.

Additionally, in connection with the Private Placement, the Company entered into a warrant amendment (the “Warrant Amendment”), dated May 17, 2023 with the holder named therein, pursuant to which the Company agreed to amend certain existing warrants to purchase up to an aggregate of 19,999 shares of Common Stock that were previously issued in January 2021 through February 2021 at an exercise price of \$636.00 per share after the 1-to-20 reverse stock split, such that effective upon the closing of the Private Placement the amended warrants have a reduced exercise price of \$10.80 per share, at an additional offering price of \$1.875 per amended warrant. The Company calculated an incremental fair value of approximately \$0.1 million by calculating the fair value of the warrants immediately before and immediately after the modification. The Company recognized the change in the fair value of the warrants as an equity issuance cost.

The Private Placement resulted in net proceeds of approximately \$3.0 million, inclusive of issuance costs of \$0.5 million and exclusive of warrant issuance costs of \$0.2 million.

Note 12 – Restructuring

In January 2023, the Company commenced a strategic restructuring program aimed at capital preservation. In April 2023, the Company approved the implementation of additional cost cutting measures, including an executive reorganization and other cuts in clinical expenses, in connection with its ongoing efforts to reduce operating expenses. In addition, the non-management members of the Board agreed to defer their Board fees until a future date. During the three and nine months ended September 30, 2023, the Company recorded charges of \$0 and \$1,517, respectively, related to the strategic restructuring program. Of that amount, the Company paid the remaining \$94 during the three months ended September 30, 2023.

The components of the restructuring charges included in the condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2023 were as follows:

	Employee Severance and Other Benefits (1)
Restructuring expenses- Sales and Marketing	\$ 566
Restructuring expenses- Research and Development	449
Restructuring expenses- General and Administrative	<u>502</u>
Total restructuring charges	\$ <u>1,517</u>

Note 13 – Subsequent Events

On November 2, 2023, the Company effected the 2023 Reverse Stock Split and as part of the adjustment to reflect the 2023 Reverse Stock Split, the Company will be paying a de minimus cash payout to stockholders who would otherwise be entitled to a fractional share of common stock. See Note 3 for further discussion.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Quarterly Report, particularly those under "Risk Factors."

All share amounts presented in this Item 2 give effect to the 1-for-15 reverse stock split of our outstanding shares of common stock, par value \$0.0001 per share ("common stock"), that occurred on November 2, 2023.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our limited operating history and need for additional capital and need for additional capital;
- our ability to execute our strategic restructuring program aimed at capital preservation, reduction in cash expenditures and reduction of our workforce;
- our ability to enter into and consummate strategic alternatives, including any acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other strategic transactions;
- our history of operating losses in each year since inception and expectation that we will continue to incur operating losses for the foreseeable future;
- our current and future capital requirements to support our development and commercialization efforts for the Pure-Vu System and our ability to satisfy our capital needs;
- our ability to remain compliant with the requirements of The Nasdaq Capital Market for continued listing;
- our dependence on the Pure-Vu System, our sole product;
- our ability to commercialize the Pure-Vu System;
- our Pure-Vu System and the procedure to cleanse the colon in preparation for colonoscopy are not currently separately reimbursable through private or governmental third-party payors;

- our ability to obtain approval or certification from regulatory agents or other competent entities in different jurisdictions for the Pure-Vu System;
- our dependence on third-parties to manufacture the Pure-Vu System;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executives and medical and science personnel;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements;
- our ability to adequately support growth;
- our ability to predict the financial impact of inflation on costs such as labor, freight and materials;
- our ability to project in the short term the hospital medical device environment considering the global pandemic and strains on hospital systems; and
- the impact of the events occurring in the Middle East and the conflict taking place in Israel

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see “Part II—Item 1A—Risk Factors” for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Overview

We have developed the Pure-Vu System, a medical device that has been cleared by the U.S. Food and Drug Administration (the “FDA”) to help facilitate the cleansing of a poorly prepared gastrointestinal tract during colonoscopy and to help facilitate upper gastrointestinal (“GI”) endoscopy procedures. The Pure-Vu System is also CE marked in the European Economic Area (EEA) for use in colonoscopy. The Pure-Vu System integrates with standard and slim colonoscopes, as well as gastroscopes, to improve visualization during colonoscopy and upper GI procedures while preserving established procedural workflow and techniques. Through irrigation and evacuation of debris, the Pure-Vu System is designed to provide better-quality exams. Challenges exist for inpatient colonoscopy and endoscopy, particularly for patients who are elderly, with comorbidities, or active bleeds, where the ability to visualize, diagnose and treat is often compromised due to debris, including fecal matter, blood, or blood clots. We believe this is especially true in high acuity patients, like GI bleeding where the existence of blood and blood clots can impair a physician’s view and removing them can be critical in allowing a physician the ability to identify and treat the source of bleeding on a timely basis. We believe use of the Pure-Vu System may lead to positive outcomes and lower costs for hospitals by safely and quickly improving visualization of the colon and upper GI tract, potentially enabling effective diagnosis and treatment without delay. In multiple clinical studies to date, involving the treatment of challenging inpatient and outpatient cases, the Pure-Vu System has consistently helped achieve adequate bowel cleanliness rates greater than 95% following a reduced prep regimen. We also believe that the technology may be useful in the future as a tool to help reduce user dependency on conventional pre-procedural bowel prep regimens. Based on our review and analysis of the latest market data for the US and Europe as obtained from iData Research Inc., we believe that during 2022 approximately 1.5 million inpatient colonoscopy procedures were performed in the U.S. and approximately 4.8 million worldwide. Upper GI bleeds occurred in the U.S. at a rate of approximately 400,000 cases per year in 2019, according to iData Research Inc. The Pure-Vu System has been assigned an ICD-10 code in the US. The system does not currently have unique codes with any private or governmental third-party payors in any other country or for any other use; however, we may pursue reimbursement activities in the future, particularly in the outpatient colonoscopy market. We received 510(k) clearance in October 2023 from the FDA for the Pure-Vu EVS System for use in the Upper GI tract as well as an enhanced version for the colon. We expect to begin market introduction of these products in the coming months. The Company does not expect to generate significant revenue from product sales until it further expands its commercialization efforts, which is subject to significant uncertainty.

Recent Developments

We continue to explore a range of strategic and financing alternatives focused on maximizing stockholder value and supporting the commercialization of the Pure-Vu System. Such potential strategic alternatives may include, among others, an acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other strategic transactions. To support these objectives, we commenced a strategic restructuring program in Q1 2023 aimed at capital preservation which was completed in Q3 2023. See Note 12 for further detail of the restructuring program. To date, the Company's operations in Israel have not been significantly impacted by the terrorist attack on Israel on October 7, 2023 and the ongoing conflict.

We continue to execute on our initiatives and have not only submitted but received FDA 510(k) clearance in October 2023 of the Upper GI Pure Vu EVS device and well as the next generation device for the colon that leverages some of the technology enhancements created during the Upper GI development process. These enhancements include a push on cleansing head and the elimination of the oversleeve covering the scope. These enhancements are designed to simplify the loading, improve the ergonomics when navigating the GI tract by allowing the physician to hold the scope directly as they normally would. The enhancements also have the benefit of reducing the cost of goods of the disposable portion of the system by approximately 50% compared to the current EVS device.

Financial Operations Overview

We have generated limited revenues to date from the sale of products. We have never been profitable and have incurred significant net losses each year since our inception, including a net loss of \$10.1 million for the nine months ended September 30, 2023, and we expect to continue to incur net operating losses for the foreseeable future. As of September 30, 2023, we had \$5.7 million in cash and cash equivalents and an accumulated deficit of \$151.4 million. In January and April 2023, we committed to a restructuring initiative designed to position us to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. If a strategic transaction is not completed, or if additional financing is not available, we may not be able to service our outstanding indebtedness and our payables and may have to file for bankruptcy protection or pursue a dissolution and liquidation of all of our remaining assets. In such an event, the amount of cash available for distribution to our shareholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations and service our outstanding indebtedness. We cannot provide assurance as to the amount of cash that would be available to distribute to shareholders, if any, after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution, if any. Such conditions raise substantial doubts about our ability to continue as a going concern.

We continue to seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties and evaluating other strategic alternative transactions including, but not limited to, an acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other transactions. The sale of equity and convertible debt securities may result in dilution to our shareholders and certain of those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our product and clinical development programs as well as commercial activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital or execute a strategic transaction as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so. Additionally, the effects of inflation on costs such as labor, freight, and materials as well as the ongoing volatility in the financial markets may negatively affect the financial performance and the liquidity of the business.

Critical Accounting Policies and Estimates

Our accounting policies are essential to understanding and interpreting the financial results reported on the condensed consolidated financial statements. The significant accounting policies used in the preparation of our condensed consolidated financial statements are summarized in Note 3 to the consolidated financial statements and notes thereto found in our Annual Report on Form 10-K for the year ended December 31, 2022. Certain of those policies are considered to be particularly important to the presentation of our financial results because they require us to make difficult, complex or subjective judgments, often as a result of matters that are inherently uncertain.

During the nine months ended September 30, 2023, there were no material changes to matters discussed under the heading “Critical Accounting Policies and Significant Judgement and Estimates” in Part II, Item 7 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

Results of Operations

Comparison of Three Months Ended September 30, 2023 and 2022

Revenue

Revenue totaled \$86.0 thousand for the three months ended September 30, 2023, compared to \$278.0 thousand for the three months ended September 30, 2022. The \$192.0 thousand decrease was attributed to a decrease in sales of the EVS product line, due to our reduced sales force from our restructuring in 2023.

Cost of Revenue

Cost of revenue for the three months ended September 30, 2023 totaled \$48.0 thousand, compared to \$83.0 thousand for the three months ended September 30, 2022. The decrease of \$35.0 thousand was primarily attributed to a decrease of \$61.0 thousand in the disposable evaluation and commercial units sold partially offset with an increase to inventory impairment of \$26.0 thousand.

Research and Development

Research and development expenses include cash and non-cash expenses relating to the advancement of our development and clinical programs for the Pure-Vu System. We have research and development capabilities in electrical and mechanical engineering with laboratories in our facility in Israel for development and prototyping, and electronics design and testing. We also use consultants and third-party design houses to complement our internal capabilities.

Research and development expenses for the three months ended September 30, 2023 totaled \$0.7 million, compared to \$1.6 million for the three months ended September 30, 2022. The decrease of \$0.9 million was primarily attributable to decreases of \$0.2 million in clinical trial and related costs and \$0.5 million in salaries and other personnel related costs, \$0.1 million in stock compensation expense and \$0.1 million in other research and development cost.

Sales and Marketing

Sales and marketing expenses include cash and non-cash expenses primarily related to our sales and marketing personnel and infrastructure supporting the commercialization of the second generation Pure-Vu System.

Sales and marketing expenses for the three months ended September 30, 2023 totaled \$0.2 million, compared to \$1.3 million for the three months ended September 30, 2022. The decrease of \$1.1 million was primarily attributable to decreases of \$0.8 million in salaries and other personnel related costs, \$0.1 million in tradeshow and demonstration units, \$0.1 million in professional services and \$0.1 million in other sales and marketing costs.

General and Administrative

General and administrative expenses consist primarily of costs associated with our overall operations and being a public company. These costs include personnel, legal and financial professional services, insurance, investor relations, compliance related fees, and expenses associated with obtaining and maintaining patents.

General and administrative expenses for the three months ended September 30, 2023 totaled \$1.6 million, compared to \$2.0 million for the three months ended September 30, 2022. The \$0.4 million decrease is primarily attributed to a decrease \$0.2 million in salaries and other personnel related costs and of \$0.2 million in stock compensation.

Other Income and Expenses

Other expense, net for the three months ended September 30, 2023 and 2022 totaled \$0.3 million, respectively.

Comparison of Nine Months Ended September 30, 2023 and 2022

Revenue

Revenue totaled \$255.0 thousand for the nine months ended September 30, 2023, compared to \$483.0 thousand for the nine months ended September 30, 2022. The decrease of \$228.0 thousand is primarily attributed to a decrease in sales of the EVS product, due to our reduced sales force from our restructuring in 2023.

Cost of Revenue

Cost of revenue for the nine months ended September 30, 2023 totaled \$283 thousand, compared to \$325.0 thousand for the nine months ended September 30, 2022. The decrease of \$42.0 thousand was primarily attributed to a net decrease of \$104.0 thousand in the system disposable evaluation and commercial units sold partially offset by an increase of \$62.0 thousand in inventory impairment.

Research and Development

Research and development expenses for the nine months ended September 30, 2023 totaled \$2.9 million, compared to \$4.3 million for the nine months ended September 30, 2022. The decrease of \$1.4 million was primarily attributable to decreases of \$0.6 million in salaries and personnel costs, \$0.3 million in clinical studies, \$0.2 million in professional services costs, \$0.2 million in stock compensation and \$0.1 million in other research and development costs.

Sales and Marketing

Sales and marketing expenses for the nine months ended September 30, 2023 totaled \$1.4 million, compared to \$3.6 million for the nine months ended September 30, 2022. The decrease of \$2.2 million was primarily attributable to decreases of \$1.4 million in salaries and other personnel related cost to support our commercialization efforts of the Pure-Vu System, \$0.2 million in demonstration product and \$0.2 million in conference and tradeshow expense, \$0.2 million in share-based compensation and \$0.2 million other travel and sales and marketing costs.

General and Administrative

General and administrative expenses for the nine months ended September 30, 2023 totaled \$5.1 million, compared to \$6.2 million for the nine months ended September 30, 2022. The decrease of \$1.1 million was primarily attributable to decreases of \$0.7 million in share-based compensation, \$0.1 million in professional and investor and public relation fees, \$0.1 million in insurance costs and \$0.1 million in travel costs and other general and administrative costs.

Other Income and Expenses

Other expense, net for the nine months ended September 30, 2023 totaled \$0.6 million compared to \$1.1 million for the nine months ended September 30, 2022. The decrease of \$0.5 million in other expense, net was primarily attributable to an decrease of \$0.3 million in finance expense and an increase of \$0.1 million in gain on change in the fair value of contingent royalty.

Liquidity and Capital Resources

To date, we have generated minimal revenues, experienced negative operating cash flows and have incurred substantial operating losses from our activities. We expect operating costs will increase significantly as we incur costs associated with commercialization activities related to the Pure-Vu System. As described above under “Overview” and “Financial Operations Overview,” we adopted a restructuring program in January and April 2023 intended to reduce our operating costs and other expenses and have commenced a process of evaluating strategic alternatives. If a strategic transaction is not completed, or if additional financing is not available, we may not be able to service our outstanding indebtedness and our payables and may have to file for bankruptcy protection or pursue a dissolution of the company and liquidation of all of our remaining assets. In such an event, the amount of cash available for distribution to our shareholders, if any, would depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution may be reduced as we continue to fund our operations and service our outstanding indebtedness. Further, we cannot provide assurance as to the amount of cash that would be available to distribute to shareholders, if any, after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution, if any. We expect to continue to fund our operations primarily through utilization of our current financial resources, future product sales, the issuance of debt or equity, as well as through potential strategic alternative transactions. As of September 30, 2023, our accumulated deficit was \$151.4 million. Such conditions raise substantial doubt about our ability to continue as a going concern. The accompanying unaudited condensed consolidated financial statements do not include any adjustments that may result from this uncertainty.

On May 17, 2023, the Company entered into a securities purchase agreement with an accredited investor pursuant to which it agreed to issue and sell in a private placement an aggregate of (i) 35,000 shares of common stock, (ii) warrants to purchase up to 241,134 shares of common stock (the “Pre-Funded Warrants”) and (iii) warrants to purchase up to 276,134 shares of common stock (the “Common Warrants”). The purchase price was \$12.765 for each share of common stock and \$12.674 for each Pre-Funded Warrant, resulting in net proceeds of approximately \$3.0 million, inclusive of issuance costs of \$0.5 million and exclusive of warrant issuance costs of \$0.2 million. See Note 11 for further discussion of the Private Placement.

Rising inflation, rising interest rates, and financial market volatility may adversely impact our ability to enter into, modify, and negotiate favorable terms and conditions relative to equity and debt financing initiatives. The uncertain financial markets, potential disruptions in supply chains, and changing priorities could also affect our ability to enter into key agreements. These disruptions may negatively impact our future sales, results of operations, financial condition, and liquidity.

Our ability to continue as a going concern for the next twelve months from the issuance of our Quarterly Report on Form 10-Q, depends on our ability to execute our business plan, increase revenue and reduce expenditures. As of September 30, 2023, we had cash and cash equivalents of \$5.7 million and an accumulated deficit of \$151.4 million. Based on our current business plan, we believe our cash and cash equivalents as of September 30, 2023 will be sufficient to meet our anticipated cash requirements into the fourth quarter of 2023. We will need to raise significant additional capital to continue to fund operations. We may seek to sell common or preferred equity, convertible debt securities or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants, as well as evaluate other strategic alternative transactions. The sale of equity and convertible debt securities may result in dilution to our shareholders and certain of those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our product and clinical development programs as well as commercial activities. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate expenses including those associated with our planned product development, clinical trial and commercial efforts.

These factors raise substantial doubt about our ability to continue as a going concern. For more information, refer to Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

As of September 30, 2023, we had total current assets of \$6.7 million and total current liabilities of \$4.5 million resulting in working capital of \$2.2 million. Net cash used in operating activities for the nine months ended September 30, 2023 was \$9.3 million, which includes a net loss of \$10.1 million, offset by non-cash expenses principally related to share-based compensation expense of \$0.4 million, depreciation and amortization of \$0.3 million, amortization of debt issuance costs of \$0.2 million, and inventory impairment of \$0.2 million, offset by changes in net working capital items principally related to the decrease in prepaid expenses and other current assets of \$0.3 million, accounts payable and accrued expenses of \$0.5 million and operating lease liabilities of \$0.2 million.

Net cash used in investing activities for the nine months ended September 30, 2023 totaled \$0.1 million related to the purchase of fixed assets.

Net cash provided by financing activities for the nine months ended September 30, 2023 totaled \$1.1 million related to proceeds from issuance of common shares pursuant to at-the-market issuance registered offerings of \$0.1 million and \$3.5 million in proceeds from a private placement offering, offset by \$2.0 million in repayments under term loans and financing fees related to the at-the-market offering and private placement offering of \$0.5 million.

As of September 30, 2023, we had cash and cash equivalents of \$5.7 million. We will need to raise significant additional capital to continue to fund operations. We may seek to sell common or preferred equity, convertible debt securities or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants, as well as evaluate other strategic alternative transactions.

Shelf Registration Statement

On March 16, 2021, we filed a shelf registration statement (File No. 333-254343) with the Securities and Exchange Commission (the “2021 Shelf Registration Statement”), which was declared effective on March 26, 2021, that allows us to offer, issue and sell up to a maximum aggregate offering price of \$100.0 million of any combination of our common stock, preferred stock, warrants, debt securities, subscription rights and/or units from time to time, together or separately, in one or more offerings. As of September 30, 2023, we have not sold any securities under the 2021 Shelf Registration Statement, except as described below.

The 2021 Shelf Registration Statement includes a prospectus registering an at-the-market offering program pursuant to an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Oppenheimer & Co. Inc. (“Oppenheimer”), entered into in March 2021, under which Oppenheimer may offer and sell from time to time shares of our common stock having an aggregate offering price of up to \$25.0 million, subject to the provisions of General Instruction I.B.6 of Form S-3, which provides that we may not sell securities in a public primary offering with a value exceeding one-third of our public float in any twelve-month period (approximately \$8.8 million beginning effective as of March 29, 2022, the date of filing of our most recent Annual Report on Form 10-K) unless our public float is at least \$75 million. If our public float meets or exceeds \$75.0 million at any time, we will no longer be subject to the restrictions set forth in General Instruction I.B.6 of Form S-3, at least until the filing of our next Section 10(a)(3) update as required under the Securities Act.

During the nine months ended September 30, 2023, we sold approximately 7,942 shares of our common stock under the Equity Distribution Agreement, resulting in net cash proceeds of \$102 thousand, after deducting issuance costs of \$19 thousand. We did not have any sales under this agreement during the three months ended September 30, 2023 or during the period after September 30, 2023.

Our ability to issue securities is subject to market conditions and other factors including, in the case of our debt securities, our credit ratings.

Long Term Debt

On July 16, 2021 (the “Effective Date”), we entered into a loan facility (the “Kreos Loan Agreement”) with Kreos Capital VI (Expert Fund) LP (the “Lender”). Under the Kreos Loan Agreement, the Lender has agreed to provide us with access to term loans in an aggregate principal amount of up to \$12.0 million (the “Loan”) in three tranches as follows: (a) on the Effective Date, a loan in the aggregate principal amount of \$4 million (the “Convertible Note”, or “Tranche A”), (b) on the Effective Date, a loan in the aggregate principal amount of \$5 million (“Tranche B”), and (c) available until December 31, 2021, a loan in the aggregate principal amount of \$3 million (“Tranche C”). The Kreos Loan Agreement contains customary representations and warranties, indemnification provisions in favor of the Lender, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. Outstanding borrowings under the Loan are secured by a first priority security interest on substantially all of our personal property assets, including our material intellectual property and equity interests in its subsidiaries. There are no liquidity or financial covenants.

The Convertible Note and Tranche B were funded on the Effective Date. As of December 31, 2021, we drew down the full \$3 million aggregate principal amount of Tranche C.

The Convertible Note requires forty-eight monthly interest only payments at 7.75% per annum commencing after the Effective Date and thereafter full payment of the then outstanding principal balance of the Convertible Note on July 1, 2025. The Kreos Loan Agreement contains features that would permit the Lender to convert all or any portion of the outstanding principal balance of the Convertible Note at any time, pursuant to which the converted part of the Convertible Note will be converted into that number of shares of our common stock to be issued to the Lender at a price per share equal to the conversion price, of \$28 per share. Following the conversion of any portion of the outstanding principal balance of the Convertible Note, the principal balance of the Convertible Note remaining outstanding shall continue to bear interest at 7.75% per annum. As of September 30, 2023, the outstanding principal balance of the Convertible Note was \$4.0 million.

The Tranche B loan requires interest only monthly payments commencing on the Effective Date until September 30, 2022 and, thereafter, thirty-three monthly payments of principal and interest accrued thereon until June 1, 2025. The Tranche C loan requires interest only monthly payments commencing on the date of the draw down until September 30, 2022 and, thereafter, thirty-two monthly payments of principal and interest accrued thereon until June 1, 2025. As of September 30, 2023, the outstanding principal balance of the Tranche B loan and the Tranche C loan in aggregate is \$5.3 million.

In connection with the Kreos Loan Agreement, we also issued to the Lender a warrant (“Warrant”), dated July 16, 2021, to purchase up to 9,547 shares of our common stock, at an exercise price of \$20.948 per share, payable in cash or on a cashless basis according to the formula set forth in the Warrant. The exercise price of the Warrant and the number of shares issuable upon exercise of the Warrant are subject to adjustments for stock splits, combinations, stock dividends or similar events. The Warrant is exercisable until the date that is ten years after the date of issuance.

The non-current portion of our long-term debt amounted to \$2.5 million as of September 30, 2023, compared to \$2.8 million as of December 31, 2022. We believe that at September 30, 2023 we were, and that we currently are, in compliance with all of our long-term debt covenants.

The sale of equity and convertible debt securities may result in dilution to our shareholders and certain of those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our product and clinical development programs as well as commercial activities. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate expenses including those associated with our planned product development, clinical trial and commercial efforts.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer, Chief Financial Officer, and Chief Accounting Officer evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any 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. Our Chief Executive Officer, Chief Financial Officer, and Chief Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, we believe would individually or in the aggregate have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, for the year ended December 31, 2022 may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company’s business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 31, 2023.

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

Unregistered Sales of Equity Securities

None.

Securities Act Exemptions

We deemed the offers, sales and issuances of the securities described above to be exempt from registration under the Securities Act of 1933, as amended (the “Securities Act”), in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering.

All certificates representing the securities issued in the transactions described above included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Certificate of Amendment of Certificate of Incorporation, as amended, of Motus GI Holdings, Inc., dated November 1, 2023.	8-K	001-38389	3.1	11/2/2023	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).					X
31.3	Certification of Chief Accounting Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).					X
32.1**	Certification of Chief Executive Officer, Chief Financial Officer, and Chief Accounting Officer pursuant to 18 U.S.C. Section 1350).					X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101).					X

** Furnished, not filed.

SIGNATURES

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

Motus GI Holdings, Inc.
(Registrant)

Date: November 13, 2023

By: /s/ Mark Pomeranz
Name: Mark Pomeranz
Title: *Chief Executive Officer*
(Principal Executive Officer)

Date: November 13, 2023

By: /s/ Ravit Ram
Name: Ravit Ram
Title: *Chief Financial Officer*
(Principal Financial Officer)

Date: November 13, 2023

By: /s/ Elad Amor
Name: Elad Amor
Title: *Chief Accounting Officer*
(Principal Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Pomeranz, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023 of Motus GI Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Mark Pomeranz

Mark Pomeranz
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ravit Ram, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023 of Motus GI Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Ravit Ram

Ravit Ram
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF CHIEF ACCOUNTING OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Elad Amor, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023 of Motus GI Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Elad Amor

Elad Amor
Chief Accounting Officer
(Principal Accounting Officer)

**Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Motus GI Holdings, Inc. for the period ended September 30, 2023 (the "Report"), each of the undersigned hereby certifies in his capacity as an officer of Motus GI Holdings, Inc. (the "Company") that to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 13, 2023

By: /s/ Mark Pomeranz
Mark Pomeranz
Chief Executive Officer
(Principal Executive Officer)

Dated: November 13, 2023

By: /s/ Ravit Ram
Ravit Ram
Chief Financial Officer
(Principal Financial Officer)

Dated: November 13, 2023

By: /s/ Elad Amor
Elad Amor
Chief Accounting Officer
(Principal Accounting Officer)

This Certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted 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, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Motus GI Holdings, Inc. and will be retained by Motus GI Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
