

**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 March 31, 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 May 01, 2023, 4,778,873 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)

	March 31, 2023 <u>(unaudited)</u>	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,648	\$ 14,042
Accounts receivable	52	59
Inventory, current	464	488
Prepaid expenses and other current assets	1,093	781
Total current assets	<u>10,257</u>	<u>15,370</u>
Fixed assets, net	1,237	1,325
Inventory, non-current	334	511
Right-of-use assets	390	428
Other non-current assets	13	13
Total assets	<u>\$ 12,231</u>	<u>\$ 17,647</u>
<b>Liabilities and Shareholders' (Deficiency) Equity</b>		
Current liabilities:		
Current portion of long-term debt, net of unamortized debt discount of \$168 and \$182, respectively	\$ 2,611	\$ 2,532
Accounts payable and accrued expenses	1,472	1,969
Operating lease liabilities - current	248	245
Other current liabilities	47	53
Total current liabilities	<u>4,378</u>	<u>4,799</u>
Convertible note, net of unamortized debt discount of \$94 and \$108, respectively	3,906	3,892
Long-term debt, net of unamortized debt discount of \$104 and \$135, respectively	3,904	4,589
Contingent royalty obligation	992	1,212
Operating lease liabilities - non-current	136	178
Total liabilities	<u>13,316</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; 4,778,873 and 4,659,769 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	-	-
Additional paid-in capital	144,652	144,328
Accumulated deficit	(145,737)	(141,351)
Total shareholders' (deficiency) equity	<u>(1,085)</u>	<u>2,977</u>
Total liabilities and shareholders' (deficiency) equity	<u>\$ 12,231</u>	<u>\$ 17,647</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
Revenue	\$ 56	\$ 20
Operating expenses:		
Cost of revenue - sales	9	15
Cost of revenue - impairment of inventory	165	159
Research and development	1,454	1,275
Sales and marketing	842	983
General and administrative	1,945	2,114
Total costs and expenses	4,415	4,546
<b>Loss from Operations</b>	<b>(4,359)</b>	<b>(4,526)</b>
Gain on change in estimated fair value of contingent royalty obligation	220	29
Finance expense, net	(239)	(332)
Foreign currency (loss) gain	(8)	18
Net loss	\$ (4,386)	\$ (4,811)
Basic and diluted loss per common share:	\$ (0.92)	\$ (1.86)
Weighted average number of common shares outstanding, basic and diluted	4,763,210	2,589,712

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	<u>Common Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total shareholders' deficiency</u>
	<u>Shares</u>	<u>Amount</u>			
Balance at January 1, 2023	4,659,769	\$ -	\$ 144,328	\$ (141,351)	\$ 2,977
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of \$19	119,104	-	102	-	102
Share based compensation	-	-	222	-	222
Net loss	-	-	-	(4,386)	(4,386)
Balance at March 31, 2023	<u>4,778,873</u>	<u>\$ -</u>	<u>\$ 144,652</u>	<u>\$ (145,737)</u>	<u>\$ (1,085)</u>

	<u>Common Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total shareholders' equity</u>
	<u>Shares</u>	<u>Amount</u>			
Balance at January 1, 2022	2,416,021	\$ -	\$ 132,411	\$ (122,754)	\$ 9,657
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of \$111	298,761	-	3,005	-	3,005
Issuance of common shares upon vesting of restricted stock units	13,721	-	-	-	-
Issuance of common stock for board of directors' compensation	24,458	-	235	-	235
Share based compensation	-	-	521	-	521
Net loss	-	-	-	(4,811)	(4,811)
Balance at March 31, 2022	<u>2,752,961</u>	<u>\$ -</u>	<u>\$ 136,172</u>	<u>\$ (127,565)</u>	<u>\$ 8,607</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,386)	\$ (4,811)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	117	124
Amortization of debt issuance costs	62	59
Gain on change in estimated fair value of contingent royalty obligation	(220)	(29)
Share based compensation	222	521
Impairment of inventory	165	159
Issuance of common stock for board of directors' compensation	-	57
Amortization on operating lease right-of-use asset	73	79
Changes in operating assets and liabilities:		
Accounts receivable	7	91
Inventory	22	(376)
Prepaid expenses and other current assets	(312)	(378)
Accounts payable and accrued expenses	(472)	(658)
Operating lease liabilities - current and non-current	(74)	(82)
Other current and non-current liabilities	(6)	(2)
Net cash used in operating activities	(4,802)	(5,246)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of fixed assets	(39)	(1)
Net cash used in investing activities	(39)	(1)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common shares	121	3,116
Repayment of debt	(655)	-
Equity financing fees	(19)	(94)
Net cash (used in) provided by financing activities	(553)	3,022
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	(5,394)	(2,225)
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	14,042	22,563
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	\$ 8,648	\$ 20,338
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
<b>CASH PAID FOR:</b>		
Interest	\$ 246	\$ 244
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:</b>		
Common stock issued for prepaid board of directors' compensation	\$ -	\$ 178
Reclassification of prepaid expenses to fixed assets	\$ -	\$ 4
Reclassification of inventory to fixed assets	\$ 14	\$ 12
Purchase of fixed assets in accounts payable and accrued expenses	\$ -	\$ 45
Financing fees included in accounts payable and accrued expenses	\$ -	\$ 17
Right-of-use asset obtained in exchange for lease obligation	\$ 35	\$ 35
Prepaid expenses resulting from right-of-use asset obtained	\$ -	\$ 3

The accompanying notes are an integral part of these condensed consolidated financial statements.

**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 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. The Company received 510(k) clearance in February 2022 from the FDA for the Pure-Vu EVS System and has commenced commercialization of this product. 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 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 \$4.4 million for the three months ended March 31, 2023. The Company expects to continue to incur net operating losses for the foreseeable future. Net cash used in operating activities for the three months ended March 31, 2023 was \$4.8 million. As of March 31, 2023, the Company had cash and cash equivalents of \$8.6 million and an accumulated deficit of \$145.7 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 doubts about the Company’s ability to continue as a going concern.

The Company has financed its operations primarily through sales of equity-related securities. 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 three months ended March 31, 2023, the Company sold approximately 119 thousand shares of our common stock under this agreement, resulting in net cash proceeds of \$102 thousand, after deducting issuance costs of \$19 thousand.

### **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 three months ended March 31, 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 three months ended March 31, 2023.

#### **Reverse Stock Split**

On July 25, 2022, 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-20. 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.

Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the 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.



### **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 consolidated financial statements.

#### Note 4 –Fair Value Measurements

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

	March 31, 2023			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities</b>				
Contingent royalty obligation	\$ -	\$ -	\$ 992	\$ 992

  

	December 31, 2022			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities</b>				
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.

In estimating the fair value of the Company's contingent royalty obligation, the Company used the discounted cash flow method as of March 31, 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.

Changes in the fair value of recurring fair value measurements using significant unobservable inputs (Level 3), which solely consisted of a contingent royalty obligation, during the three months ended March 31, 2023 was as follows:

	Fair Value Measurements of Contingent Royalty Obligation (Level 3)
Balance at December 31, 2022	\$ 1,212
Change in estimated fair value of contingent royalty obligation	(220)
Balance at March 31, 2023	\$ 992

The contingent royalty obligation is re-measured at each balance sheet date 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 March 31, 2023 and December 31, 2022, respectively), and 5) rate of royalty payment (3% as of March 31, 2023 and December 31, 2022).

In accordance with ASC-820-10-50-2(g), the Company performed a sensitivity analysis of the liability, which was classified as a Level 3 financial instrument. The Company recalculated the fair value of the liability by applying a +/- 2% change to the input variable in the discounted cash flow model; the discount rate. A 2% decrease in the discount rate would increase the liability by \$94 and a 2% increase in the discount rate would decrease the liability by \$84. Such amounts are based on highly sensitive estimates and actual results could result in material change in future periods.

#### 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 months ended March 31, 2023 and 2022, an inventory impairment of \$165 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 March 31, 2023 and December 31, 2022 consisted of the following:

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
Raw materials	\$ 497	\$ 697
Work-in-process	164	155
Finished goods	703	548
Inventory reserve	(566)	(401)
Inventory, net	<u>\$ 798</u>	<u>\$ 999</u>
Inventory, current	\$ 464	\$ 488
Inventory, non-current	<u>\$ 334</u>	<u>\$ 511</u>

**Note 6 – Fixed assets, net**

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

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
Office equipment	\$ 171	\$ 171
Computers and software	321	321
Machinery	1,052	1,049
Lab and medical equipment	1,503	1,477
Leasehold improvements	200	200
Total	3,247	3,218
Less: accumulated depreciation and amortization	(2,010)	(1,893)
Fixed assets, net	<u>\$ 1,237</u>	<u>\$ 1,325</u>

Depreciation and amortization expense for the three months ended March 31, 2023 and 2022 was \$117 and \$124, respectively.

**Note 7 – Leases**

The Company leases offices in Fort Lauderdale, Florida and Israel which expire in November 2024 and December 2023, respectively.

The Company 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:

	<b>Three Months Ended March 31, 2023</b>	<b>Three Months Ended March 31, 2022</b>
<b>Lease Cost</b>		
Operating lease cost, net of related party license fee	\$ 16	\$ 39
Variable lease cost	25	30
<b>Total lease cost</b>	<u>\$ 41</u>	<u>\$ 69</u>

	As of March 31, 2023	As of December 31, 2022
<b>Assets</b>		
Operating lease, right-of-use- asset	\$ 390	\$ 428
<b>Liabilities</b>		
Current		
Operating lease liabilities	\$ 248	\$ 245
Non-current		
Operating lease liabilities, net of current portion	136	178
Total lease liabilities	\$ 384	\$ 423
<b>Other information:</b>		
Weighted average remaining lease term - operating leases	1.75 years	1.79 years
Weighted-average discount rate - operating leases	7.20%	7.36%

The Company's lease expense is included in general and administrative expenses which is net of the related party license fee of \$49 and \$47 for the three months ended March 31, 2023 and 2022, respectively (see Note 10).

#### 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 \$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. 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 9,547 shares of the Company’s 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 Company concluded that the Warrant is indexed to its own stock and, accordingly is classified as equity. See Note 11 for further discussion of the Warrant.

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 three months ended March 31, 2023 and 2022, interest expense for the Loan was as follows:

	<b>Three Months Ended March 31, 2023</b>	<b>Three Months Ended March 31, 2022</b>
Contractual interest expense	\$ 246	\$ 268
Amortization of debt issuance costs	62	59
<b>Total interest expense</b>	<b>\$ 308</b>	<b>\$ 327</b>

Future principal payments under the Convertible Note as of March 31, 2023 are as follows:

<b>Years Ending December 31,</b>	<b>Amount</b>
2023	\$ -
2024	-
2025	4,000
Total future principal payments	4,000
Less unamortized debt issuance costs	(94)
Total balance – Convertible Note	<u>\$ 3,906</u>

Future principal payments under the Long-term Debt as of March 31, 2023 are as follows:

<b>Years Ending December 31,</b>	<b>Amount</b>
2023	\$ 2,059
2024	2,983
2025	1,601
Total future principal payments	6,643
End of loan payments	140
Less unamortized debt issuance costs of current portion of long-term debt	(168)
Less unamortized debt issuance costs of non-current portion of long-term debt	(100)
Total balance	<u>\$ 6,515</u>
Less long-term debt, current	<u>\$ (2,611)</u>
Long-term debt, net of current portion	<u>\$ 3,904</u>

**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.

**Manufacturing Component Purchase Obligations**

The Company utilizes two outsourcing partners to manufacture its workstation and disposable portions of the Pure-Vu System, and to perform final assembly and testing of finished products. These outsourcing partners acquire components and build product based on demand information supplied by the Company. As of March 31, 2023, the Company expects to pay \$114 under manufacturing-related supplier arrangements within the next year, substantially all of which is noncancelable.

**Other Commitments and Contingencies**

The Company has a severance contingency for severance payments to its Executives in the aggregate of \$1,428, in the event that they are terminated without cause or leave due to good reason, as outlined in their employee agreements. Management estimates that the likelihood of payment is remote; therefore, no liability was reflected in these condensed consolidated financial statements.

## 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), formerly a greater than 5% holder of the Company’s common stock and entity in which David Hochman, the Chairman of the Company’s board of directors, serves as the Chairman of the board of directors and Chief Executive Officer, and Darren Sherman, a member of the Company’s board of directors, serves as a director and as President and Chief Operating Officer. 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 months ended March 31, 2023 and 2022, the Company recorded a license fee of \$49 and \$47, respectively, in relation to the Shared Space Agreement. This amount is netted with rent expense in general and administrative expenses.

### 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 months ended March 31, 2023 and 2022:

	Three Months ended	
	March 31,	
	2023	2022
Research and development	\$ 59	\$ 97
Sales and marketing	1	58
General and administrative	162	366
Total	\$ 222	\$ 521

As of March 31, 2023, unamortized share-based compensation for stock options was \$572, with a weighted-average recognition period of 0.79 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	400,137	\$ 42.69	393,261	\$ 50.86
Expired	(249)	\$ 10.40	(54,717)	\$ 100.00
Forfeited	(24,854)	\$ 12.70	-	\$ -
Outstanding at March 31, 2023	375,034	\$ 44.70	338,544	\$ 42.91
Exercisable at March 31, 2023	318,094	\$ 50.04	338,544	\$ 42.91

As of March 31, 2023, there were 16,606 nonvested restricted stock unit awards at a weighted average grant date fair value of \$16.17. As of December 31, 2022, there were 20,278 nonvested restricted stock unit awards at a weighted average grant date fair value of \$18.62.

As of March 31, 2023, unamortized stock compensation for restricted stock units was \$233, with a weighted-average recognition period of 0.76 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 6,000 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 \$56.60 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 6,000 shares of common stock of the Company exercisable at a price equal to \$10 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 three months ended March 31, 2023 and 2022, 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.

### Note 12 – Restructuring

In January 2023, the Company commenced a strategic restructuring program aimed at capital preservation. It reduced its quarterly cash expenditures by approximately 35% by eliminating approximately 45% of its workforce during the first quarter of 2023. In addition, the non-management members of the Board agreed to defer their Board fees until a future date. During the three months ended March 31, 2023, the Company recorded charges of \$1,250 related to the strategic restructuring program. Of that amount, the Company paid \$1,007 during the three months ended March 31, 2023. The Company expects to pay the remaining \$244 in the second quarter of 2023.

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. The Company expects to incur non-recurring charges related to these cost-cutting measures of approximately \$400 in the second quarter of 2023. See Note 13.



The outstanding restructuring liabilities are included in accounts payable and accrued expenses on the condensed consolidated balance sheet. As of March 31, 2023, the components of the liabilities were as follows:

	<b>Employee Severance and Other Benefits (1)</b>
Balance as of January 1, 2023	\$ -
Restructuring expenses- Sales and Marketing	453
Restructuring expenses- Research and Development	582
Restructuring expenses- General and Administrative	215
Cash payments	(1,007)
Liability included in accounts payable and accrued expenses at March 31, 2023	<u>\$ 243</u>

(1) Employee severance and other benefits expenses were included in sales and marketing expenses, research and development expenses, and general and administrative expenses in the statements of comprehensive loss.

#### **Note 13 – Subsequent Events**

In addition, in order to further reduce expenses, Andrew Taylor, our current Chief Financial Officer, intends to step down from his role as Chief Financial Officer before the end of the second quarter of 2023. We are actively putting in place an internal transition plan and intend to appoint another officer to replace Mr. Taylor as our Chief Financial Officer.

## 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."*

### 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; and
- our ability to project in the short term the hospital medical device environment considering the global pandemic and strains on hospital systems

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank or any other financial institution that is placed into receivership by the FDIC, may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if we were to borrow money in the future and if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay or perform their obligations to us or to enter into new commercial arrangements requiring additional payments to us or additional funding could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry, including for example in the case of First Republic Bank and Credit Suisse during March 2023. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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 2019 market data and 2021 projections for the U.S. 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 February 2022 from the FDA for our Pure-Vu EVS System and have commenced commercialization of this product.

## Recent Developments

In January 2023, we initiated a process to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. We engaged Lake Street Capital Markets LLC (“Lake Street Capital”) to advise us in this process. Potential strategic alternatives that we may consider are expected to include 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 aimed at capital preservation. We have reduced our quarterly cash expenditures by approximately 35% by eliminating approximately 45% of our workforce during the first quarter of 2023.

In April 2023, we 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. As part of the executive changes, Mark Pomeranz, the Company’s Chief Operating Officer, director and former Chief Executive Officer, has been appointed as the Company’s Chief Executive Officer, effective immediately. In connection with Mr. Pomeranz’s appointment, Timothy Moran has stepped down as Chief Executive Officer of the Company. Mr. Moran shall succeed David Hochman as Chairman of the Board, effective immediately. Mr. Hochman will continue to serve as an independent director of the Company, effective immediately.

## 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 loss of \$4.4 million for the three months ended March 31, 2023, and we expect to continue to incur net operating losses for the foreseeable future. As of March 31, 2023, we had \$8.6 million in cash and cash equivalents and an accumulated deficit of \$145.7 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 doubts about the Company’s 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 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 three months ended March 31, 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 March 31, 2023 and 2022*

#### **Revenue**

As of March 31, 2023, our commercial launch of the FDA-cleared Pure-Vu EVS System has generated limited revenue. We expect to generate greater revenue from product sales if and when we expand our commercialization efforts; however, this is subject to significant uncertainty.

Revenue totaled \$56.0 thousand for the three months ended March 31, 2023, compared to \$20.0 thousand for the three months ended March 31, 2022. The increase of \$36.0 thousand was primarily attributable to the sales of Pure-Vu Gen EVS disposables product.

#### **Cost of Revenue**

Cost of revenue for the three months ended March 31, 2023 totaled \$174.0 thousand, compared to \$174.0 thousand for the three months ended March 31, 2022. Cost of revenue includes the impairment of inventory of \$165.0 thousand and \$159.0 thousand during the three months ended March 31, 2023 and 2022, respectively. Impairment of inventory for the three months ended March 31, 2023 is attributed to the implementation of additional cost cutting measures and executive reorganization in April 2023. As certain developments occur in the business and operations, we anticipate further possible impairment to inventory in 2023.

#### **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 totaled \$1.5 million for the three months ended March 31, 2023 compared to \$1.3 million for the three months ended March 31, 2022. The \$0.2 million increase is primarily attributable to an increase of \$0.3 million in salaries and personnel related costs relating to our restructuring in Q1 2023, partially offset with a \$0.1 million decrease in other research and development costs.

#### **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 Pure-Vu System.

Sales and marketing expenses totaled \$0.8 million for the three months ended March 31, 2023 compared to \$1.0 million for the three months ended March 31, 2022. The decrease of \$0.2 million is primarily attributable to a decrease of \$0.2 million in marketing sample 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 March 31, 2023 totaled \$1.9 million, compared to \$2.1 million for the three months ended March 31, 2022. The decrease of \$0.2 million was primarily attributable to decreases of \$0.1 million in professional services, \$0.2 million in share-based compensation and \$0.1 million in other general and administrative costs, partially offset by increases in salaries and other personnel related costs of \$0.2 million relating to our restructuring in Q1 2023.

## 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 to evaluate strategic alternatives. In connection with the executive reorganization, in April 2023, Mark Pomeranz, our Chief Operating Officer, director and former Chief Executive Officer, was appointed as our Chief Executive Officer, and Timothy Moran stepped down as our Chief Executive Officer. In addition, in order to further reduce expenses, Andrew Taylor, our current Chief Financial Officer, intends to step down from his role as Chief Financial Officer before the end of the second quarter of 2023. We are actively putting in place an internal transition plan and intend to appoint another officer to replace Mr. Taylor as our Chief Financial Officer. 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, 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 will 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 other strategic alternative transactions. As of March 31, 2023, our accumulated deficit was \$145.7 million. Such conditions raise substantial doubt about our ability to continue as a going concern.

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 three months ended March 31, 2023, the Company sold approximately 119 thousand shares of our common stock under this agreement, resulting in net cash proceeds of \$102 thousand, after deducting issuance costs of \$19 thousand.

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. COVID-19 and government measures taken in response have also had an impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as certain medical services and supplies, have spiked, while demand for other goods and services have fallen. The future progression of the outbreak and its longer-term effects on our business and operations continue to evolve and are still uncertain. We and our third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to our research and development activities, including, for example, medical and laboratory supplies, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts related to the outbreak in certain parts of the world. 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 March 31, 2023, we had cash and cash equivalents of \$8.6 million and an accumulated deficit of \$145.7 million. Based on our current business plan, we believe our cash and cash equivalents as of March 31, 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 condensed consolidated financial statements included elsewhere in this Quarterly Report.

As of March 31, 2023, we had total current assets of \$10.3 million and total current liabilities of \$4.4 million resulting in working capital of \$5.9 million. Net cash used in operating activities for the three months ended March 31, 2023 was \$4.8 million, which includes a net loss of \$4.4 million, offset by non-cash expenses principally related to share based compensation expense of \$0.2 million, depreciation and amortization of \$0.1 million, amortization of debt issuance costs of \$0.1 million, inventory impairment of \$0.2 million, offset by changes in net working capital items principally related to the increase in prepaid expenses and other current assets of \$0.4 million, the increase in accounts payable and accrued expenses of \$0.5 million, and operating lease liabilities of \$0.1 million.

Net cash used in investing activities for the three months ended March 31, 2023 related to the purchase of fixed assets of \$39.0 thousand.

Net cash provided by financing activities for the three months ended March 31, 2023 totaled \$0.5 million related to proceeds from issuance of common shares pursuant to at-the-market issuance registered offering of \$0.1 million, offset by repayment under loan terms of \$0.6 million.

#### *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 March 31, 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 31, 2023, 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 quarter ended March 31, 2023, we sold approximately 119 thousand shares of our common stock pursuant to the above-described Equity Distribution Agreement, resulting in net cash proceeds of \$102 thousand, after deducting issuance costs of \$19 thousand.

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

#### **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 and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 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. Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures, as defined above, are effective.

#### **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 three-month period ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our principal executive officer and principal financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.



## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings.

None.

### 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.

None

### Item 3. Defaults Upon Senior Securities.

None.

### Item 4. Mine Safety Disclosures.

Not applicable.

### Item 5. Other Information.

In order to further reduce expenses, as of the date of this report, Andrew Taylor, our current Chief Financial Officer, intends to step down from his role as Chief Financial Officer before the end of the second quarter of 2023. We are actively putting in place an internal transition plan and intend to appoint another officer to replace Mr. Taylor as our Chief Financial Officer.

On May 9, 2023, we amended the compensation terms for Mark Pomeranz, our Chief Executive Officer and President, to provide for an annual salary of \$450,000 per year and an annual bonus percentage of up to 60% based on achieving certain targets established by our Board of Directors.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
4.1	<a href="#">Form of November 2018 Consultant Warrant</a>	10-Q	001-38389	4.4	11/14/2018	
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).</a>					X
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).</a>					X
32.1**	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350).</a>					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: May 10, 2023*

By: /s/ Mark Pomeranz  
Name: Timothy P. Moran  
Title: *Chief Executive Officer*  
*(Principal Executive Officer)*

*Date: May 10, 2023*

By: /s/ Andrew Taylor  
Name: Andrew Taylor  
Title: *Chief Financial Officer*  
*(Principal Financial Officer and Chief 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 March 31, 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: May 10, 2023

*/s/ Mark Pomeranz*

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Mark Pomeranz  
Chief Executive Officer  
(Principal Executive Officer)

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

I, Andrew Taylor, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 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: May 10, 2023

*/s/ Andrew Taylor*

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Andrew Taylor  
Chief Financial Officer  
(Principal Financial Officer)

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**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 March 31, 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: May 10, 2023

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

Dated: May 10, 2023

By: /s/ Andrew Taylor  
Andrew Taylor  
Chief Financial Officer  
(Principal Financial 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.

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